Effective Health Care Program

Comparative Effectiveness Review
Number 128

Oral Mechanical Bowel Preparation for Colorectal Surgery

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Comparative Effectiveness Review

Number 128

Oral Mechanical Bowel Preparation for Colorectal Surgery

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This report is based on research conducted by the Brown University Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2012-00012-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

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None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

We welcome comments on this systematic review. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Key Informants

In designing the study questions, the EPC consulted several Key Informants who represent the end-users of research. The EPC sought the Key Informant input on the priority areas for research and synthesis. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

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Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

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Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report does not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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Oral Mechanical Bowel Preparation for Colorectal Surgery

Structured Abstract

Background. Oral mechanical bowel preparation (OMBP) is often prescribed preoperatively for patients undergoing elective colorectal surgery.

Objectives. We conducted a systematic review to summarize the evidence on the comparative effectiveness (prevention of surgical complications) and safety (harms) of OMBP versus no preparation, OMBP versus enema only, and among different OMBP strategies.

Data sources. We searched MEDLINE®, the Cochrane Central Register of Controlled Trials, EMBASE™, and CINAHL® without any language restriction (last search on September 6, 2013). We also searched the U.S. Food and Drug Administration Web site (last search on May 17, 2013). We supplemented searches by asking technical experts and perusing reference lists for additional citations.

Study eligibility criteria, participants, and interventions. We included English-language full-text reports of randomized controlled trials (RCTs; ≥10 patients per arm), and nonrandomized comparative studies (NRCSs; ≥100 patients per arm) of OMBP strategies in adults or children undergoing elective colon or rectal surgery. For harms we also included cohort studies of ≥200 participants. Eligible comparative studies reported on predetermined clinical outcomes, including overall mortality, infectious outcomes, anastomotic leakage; health system and resource utilization outcomes such as readmissions after surgery or length of stay; and patient-centered outcomes such as patient satisfaction and quality of life.

Study appraisal and synthesis methods. A single investigator extracted data from each study; a second investigator verified quantitative results and intervention descriptions. We assessed the risk of bias for each outcome and the strength of the evidence following the processes described in the Agency for Healthcare Research and Quality "Methods Guide for Effectiveness and Comparative Effectiveness Reviews." We synthesized results qualitatively, and performed Bayesian pairwise and network meta-analyses. Models accounted for between-study heterogeneity.

Results. Sixty unique studies (in 65 publications) were included: 44 RCTs, 10 NRCSs, and 6 single-group cohorts; 58 studies were included in main analyses (1 retracted publication and 1 possible duplicate were excluded). Of those, 18 RCTs were included in meta-analyses comparing OMBP versus enema or no preparation for the following outcomes: overall mortality, anastomotic leakage, wound infection, peritonitis, surgical site infection, and reoperation. Credible intervals of the summary odds ratio included the null value of 1.0 (no difference) for comparisons of OMBP versus no preparation or enema for all outcomes. When comparing OMBP to no preparation, credible intervals did not exclude modest (e.g., 30-50%) effects on overall mortality, anastomotic leakage, wound infection, or peritonitis in either direction. For all other comparisons, credible intervals did not exclude even larger effects. Results were robust to extensive sensitivity analyses. Twenty-four RCTs comparing alternative active OMBP strategies

(including 1 RCT comparing inpatient vs. outpatient preparation) assessed highly diverse outcomes and most pertained to interventions that are no longer in clinical use. Evidence on the adverse events of OMBP was too poorly reported to allow definitive conclusions.

Limitations. The evidence regarding OMBP for colorectal surgery is limited in the following ways: (1) most studies enrolled small numbers of patients and reported low event rates for major clinical events; (2) studies provided limited or no information for important clinical subgroups, particularly those defined by anatomic location of surgery (colon vs. rectal surgery) and the type of surgical procedure performed (e.g., open vs. laparoscopic surgery); (3) studies comparing alternative active OMBP strategies used a large number of diverse preparation regimes and reported results for heterogeneous, often poorly defined, outcomes; (4) nonrandomized trials, and particularly observational studies, could not effectively supplement the results of randomized trials because of shortcomings in their design and analysis (e.g., diversity of outcomes and suboptimal confounding control).

Conclusions. We found weak evidence suggesting that OMBP has similar effectiveness as no preparation with respect to all-cause mortality, anastomotic leakage, wound infection, and peritonitis for patients undergoing elective colorectal surgery. However, the evidence base was too weak to confidently exclude either modest benefit or modest harm. Evidence for other outcomes and comparisons was insufficient to draw definitive conclusions. The effectiveness of alternative active OMBP strategies could not be assessed because the studies compared interventions that are no longer used. Data on harms were also too sparse for analysis. Therefore, there is a clear need for new comparative studies (both randomized and nonrandomized) of the currently used OMBP strategies.

The PROSPERO registration number of the protocol of this review is CRD42013004381.

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Executive Summary

Background

In the United States, oral mechanical bowel preparation (OMBP), defined as the use of an oral preparation given prior to surgery to clear fecal material from the bowel lumen, is often prescribed preoperatively for patients undergoing elective colorectal surgery.[1] OMBP is sometimes used as a precaution in anticipation of possible iatrogenic bowel injury during abdominal and pelvic surgeries that do not entail resection of the colon or rectum (e.g., urologic or gynecologic procedures). OMBP is also routinely prescribed prior to colonoscopy to allow maximal visualization of the intraluminal bowel during the procedure, although that use is not within the scope of this report.[2]

In 2009, more than 250,000 colorectal surgeries were recorded,[3] most commonly for cancer or diverticulitis,[4] and, in the majority of cases, in adults. In the context of colorectal surgery many have considered OMBP necessary for decreasing infectious complications, in particular by lowering anastomosis leakage rates associated with surgery.[5] Gross spillage of fecal material in the operative field increases the need for a stoma, which can impact patients' quality of life. Moreover, a stoma requires additional surgery to reverse it, and possibly other surgeries if complications such as bowel obstructions or incisional hernia arise.[6,7] Complication rates for elective colorectal surgery range between 4 and 36 percent.[8,9] A surgical site infection can substantially lengthen hospital stay from approximately 4 days to 21 days and increase costs from approximately $11,000 to $43,000.[8] Therefore, reducing complication rates of elective colorectal surgery is an important goal.

However OMBP is not risk free. Most patients start the OMBP at home the day before surgery. Elderly and frail patients may undergo OMBP in the hospital. OMBP is at the least a hassle for patients. (Some preparations are unpleasant tasting; ingesting large quantities of fluids and spending long periods on the toilet are also unpleasant.) OMBP can also lead to complications. Some patients experience vomiting and dehydration severe enough to require medical attention, or even to delay the surgery. Additionally, liquid bowel contents from OMBP use may be less safely handled during surgery than solid contents and may result in infections. Individuals who may be at greater risk of adverse effects of OMBP are the elderly (≥65 years of age) and those with comorbidities such as cardiovascular and pulmonary disease, diabetes, kidney disease, and compromised immune conditions.

OMBP for colon or rectal surgery appears to be a widespread practice in the United States. A 2003 survey found that more than 99 percent of colorectal surgeons routinely employed OMBP,[10] and a recent study (2007–09) of 24 Michigan hospitals reported use of OMBP in 86 percent of all colorectal surgeries.[11] The initial adoption of OMBP prior to colorectal surgery was based on expert opinion and observational data.[12,13] However, several recent trials (mostly conducted in Europe) failed to identify a statistically significant benefit for use of OMBP prior to colon surgery.[14,15] Citing some of these trials, the 2010 guidelines of the Canadian Society of Colon and Rectal Surgeons favored omitting OMBP in the preoperative management of patients undergoing elective open right-sided and left-sided colorectal surgical resections,[16] but deemed the evidence insufficient to support or refute omitting OMBP for patients undergoing low anterior resection (with or without diverting stomas) and those undergoing laparoscopic colorectal surgery.

In addition to uncertainty over the net benefit of OMBP, both bowel preparation strategies and adjunctive therapies have changed over time. The U.S. Food and Drug Administration

(FDA) has approved several OMBP regimens that are available over the counter. Most commonly used are large-volume (approximately 4 liters) osmotically balanced polyethylene glycol (PEG) solutions (e.g., MiraLAX®, GoLYTELY®, NuLYTELY®) or reduced-volume PEG (approximately 2 liters) plus bisacodyl (HalfLytely®). PEG solutions evacuate the bowel by washout, with no substantial fluid or electrolyte shifts.[8] Bisacodyl, a poorly absorbed diphenylmethane, stimulates colonic peristalsis. Hyperosmotic preparations (e.g., Fleet®) that draw water into the bowel to achieve washout are less used because of concern about electrolyte imbalances.[2] Older, more aggressive OMBP strategies, such as whole-gut irrigation through nasogastric tubes or multiday strategies, are no longer used.

OMBP is often administered together with several cointerventions. An enema is sometimes given the night before or the morning of surgery. Antibiotics, parenteral or oral, are also often administered preoperatively for systemic coverage and for reducing the concentration of anaerobic bacteria in the gut.[17,18] Because any of these may act synergistically or competitively with OMBP, it is important to consider potential interactions when assessing the impact of various OMBP strategies on surgical outcomes.

A recent Cochrane systematic review (covering studies up to December 1, 2010) found no benefit for OMBP in terms of anastomotic leakage, other surgical complications, or mortality for mixed populations of patients undergoing colon or rectal resection.[1] However, several studies have been published since the last search of the Cochrane Review, suggesting that an updated synthesis is needed. Furthermore, there is reason to believe that OMBP could have a different impact depending on the—

- Anatomic location of surgery. For example, colon and rectal surgeries often use different operative techniques and have different complication rates.
- Type of surgery (open vs. laparoscopic). For example, it has been suggested that preparation makes manipulation of the bowel more difficult during laparoscopic surgery.
- Whether OMBP is combined with an enema (because the latter may be adequate for preparation in some cases).

Finally, large variation in practice persists in different parts of the world, perhaps suggesting that existing syntheses of the evidence do not adequately address all major decisionmaking uncertainties.

The purpose of this review was to systematically evaluate experimental and observational evidence on the benefits and adverse events associated with the use of OMBP in patients undergoing elective colorectal surgery. We also aimed to identify patient and procedural characteristics that modify the effect of OMBP on outcomes.

Key Questions

On the basis of the original topic nomination and an extensive stakeholder-driven process of topic development and refinement, we formulated the following Key Questions to guide the review:

Key Question 1: How do various preoperative OMBP strategies compare with either no OMBP or with each other with respect to their effectiveness for preventing surgical or postsurgical complications? Does the effect vary by elective (a) right colon, (b) left colon, and (c) rectal surgery?

Key Question 2: How do various preoperative OMBP strategies compare with either no OMBP or with each other with respect to presurgical and postsurgical adverse events? How do

comparative adverse events vary (a) by OMBP strategy and (b) in subgroups of especially susceptible patients?

Methods

We performed a systematic review of the published literature using established methodologies, as outlined in the Agency for Healthcare Research and Quality (AHRQ) "Methods Guide for Effectiveness and Comparative Effectiveness Reviews" (Methods Guide[a]). We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement in the reporting of this review.[19] A full description of all review steps is included in the full report and the study protocol. The PROSPERO registration number of the protocol is CRD42013004381. PROSPERO is an international database of prospectively registered systematic reviews in health and social care.

External Stakeholder Input

A Technical Expert Panel (TEP) provided input to help refine the Key Questions, identify important issues, and define parameters for the review of evidence. The nine TEP members included representatives of professional societies, experts in colorectal surgery, experts on the preoperative preparation of patients undergoing elective surgery, and an infectious disease specialist.

Literature Search and Abstract Screening

We searched MEDLINE®, the Cochrane Central Trials Registry, EMBASE™, and CINAHL® without any language or publication date restrictions (last search on September 6, 2013). See Appendix A of the full report for the exact search queries. We also did a targeted search of the FDA Web site (last search performed on May 17, 2013). We supplemented searches by asking technical experts to provide additional relevant citations and by perusing reference lists of eligible studies, clinical practice guidelines, and narrative and systematic reviews. We requested supplementary information from OMBP preparation manufacturers. Finally, we searched the ClinicalTrials.gov Web site (last searched May 16, 2013) to identify ongoing comparative trials of alternative OMBP strategies. We did not consider unpublished data other than data included in FDA documents or ClinicalTrials.gov. Titles and abstracts were manually screened in duplicate following a standardization exercise.

Study Selection and Eligibility Criteria

Two investigators reviewed full-text articles independently for eligibility. Disagreements were resolved by consensus including at least one additional investigator.

We included English-language full-text reports of randomized controlled trials (RCTs) with at least 10 patients per arm and nonrandomized comparative studies (NRCSs) with at least 100 patients per arm in adults or children undergoing elective colon or rectal surgery. Studies reporting on both colorectal and noncolorectal surgery were included if results were presented by anatomic site, or if at least 80 percent of surgeries involved the large bowel. For harms we also included cohort studies of at least 200 participants.

[a]Available at www.effectivehealthcare.ahrq.gov/methodsguide.cfm; accessed May 11, 2013.

We defined as OMBP the use of any preparation for surgery that was administered orally or through a nasogastric tube but without need for other (e.g., endoscopic) intervention. Cointerventions could include oral or parenteral antibiotics, dietary modification, or enema. Eligible studies compared alternative OMBP strategies or OMBP versus no preparation.

We included studies reporting on a predetermined set of clinical outcomes, including overall and cause-specific survival, infectious outcomes, anastomotic leakage, planned and unplanned stomas, failed attempts to restore bowel continuity, and venous thromboembolism; health system and resource utilization outcomes, such as readmissions after surgery, reoperation, additional interventional procedures, length of stay, and admission to intensive care unit/nursing care; and patient-centered outcomes, such as patient satisfaction and quality of life. For Key Question 2 we considered the following prespecified adverse events (harms): nausea; vomiting; dehydration; electrolyte imbalance; kidney damage; emergency admissions prior to surgery; canceled, delayed, or rescheduled surgeries; allergic reactions; and seizures. Studies reporting harms were included regardless of causal attribution to OMBP.

Data Extraction

A single investigator extracted data from each study; quantitative results were verified by a second reviewer. Disagreements were resolved by consensus involving a third investigator. Following pilot testing, data were extracted into electronic forms stored in the Systematic Review Data Repository using separate forms for each Key Question.[20] We took particular care to avoid double counting (both in qualitative and quantitative analyses) when published papers reported on potentially (fully or partially) overlapping patient populations. Potential overlap was assessed on the basis of the sampling population of each study, the enrollment period for each publication, the patient selection criteria, and information on overlap provided by the authors in the published papers.

Risk of Bias and Completeness of Reporting of Individual Studies

We assessed the risk of bias for each outcome following the processes described in the Methods Guide. For RCTs, we based our assessment on items derived from the Cochrane risk-of-bias tool.[21] For NRCSs and single-group studies, we used items from the Newcastle-Ottawa tool, with the addition of items relevant to statistical analysis.[22] We provide qualitative assessments regarding publication bias based on the number of available studies, the number of studies contributing information for each outcome, sample size, and the statistical significance of reported comparisons.

Synthesis

For each Key Question, we synthesized results qualitatively and assessed whether studies were sufficiently similar to be combined in a meta-analysis.

We used both pairwise and network meta-analysis. We did pairwise meta-analyses for outcome comparisons with more than three nonoverlapping studies. For outcomes with at least six studies, we used network meta-analysis to jointly analyze evidence for “OMBP with or without enema,” “enema alone,” and “no OMBP or enema.” Studies comparing “enema alone” and “no OMBP or enema” were not in the scope of this report, and such studies (if any exist) are not included the analyses. In structural sensitivity analyses we split the “OMBP with or without enema” strategy into “OMBP alone” and “OMBP plus enema” interventions. We did not

construct or analyze networks that include comparisons between alternative "active" OMBP interventions because of substantial concerns that head-to-head studies between "active" OMBP strategies are not similar to studies included in the above network. We assessed inconsistency qualitatively, by comparing results from pairwise and network meta-analyses, because formal tests for inconsistency are known to be underpowered.

Estimation was done in the generalized linear mixed-modeling framework, with binomial families and a logit link function.[23] Models accounted for between-study heterogeneity. Primary analyses used Bayesian Markov-chain Monte Carlo methods. These methods incorporate uncertainty in the summary estimates of treatment effects more fully than frequentist methods. Prior distributions for all model parameters were noninformative and were subjected to extensive sensitivity analyses, including the use of informative priors and the use of frequentist methods (which do not require prior specification). In network meta-analyses we assumed homogeneity of the random-effects variances at the between-study level because few studies provided information for each comparison in the network. Heterogeneity was assessed based on the posterior distribution of the between-study heterogeneity parameter.

Subgroup, Metaregression, and Sensitivity Analyses

We explored between-study heterogeneity using subgroup and metaregression analyses (e.g., year of publication or items related to study risk of bias). We also performed sensitivity analyses, such as leave-one-out analyses, analyses assuming a fixed-effects model, analyses including a retracted study, and analyses evaluating alternative network topologies.

Software

All analyses were performed using Stata IC (version 12.1/SE Stata Corp., College Station, TX). We did not perform any adjustments for multiple comparisons. Markov-chain Monte Carlo estimation for Bayesian analysis was done in WinBUGS (version 1.4.3; MRC Biostatistics Unit, Cambridge, UK) through calls from Stata.

Grading the Body of Evidence and Assessing Applicability

We followed the Methods Guide to evaluate the strength of the body of evidence (high, moderate, low, or insufficient) for each Key Question with respect to the following domains: risk of bias, consistency, directness, precision, and reporting bias. We followed the Methods Guide[24] to evaluate the applicability of included studies to patient populations of interest, as guided by the Key Questions.

Results

Our literature search yielded 11,869 citations, of which 901 were reviewed in full text. Sixty unique studies (in 65 publications) were included: 44 RCTs, 10 NRCSs; and 6 single-group cohorts. Fifty-eight studies were included in main analyses. One retracted publication and one possible duplicate were excluded. (See the full report for details on the literature flow.) The most common reasons for exclusion of articles were related to study design (e.g., we excluded uncontrolled case series) and language of publication. Up to 2010 only four relevant non–English-language studies were available. These studies reported on few patients and very low numbers of events, so their inclusion would not appreciably affect our results. See Appendix B of the full report for a list of the excluded studies and reasons for exclusion. Data extraction

forms and summary tables for all included studies are available online in the Systematic Review Data Repository (http://srdr.ahrq.gov/).

Effectiveness: OMBP Versus No OMBP or Enema; Alternative OMBP Strategies (Key Question 1)

Forty-four RCTs and 10 NRCSs met criteria for Key Question 1. Forty-two of the 44 RCTs were included in main analyses. The published report of one RCT was retracted and was not included in the main analyses, and one RCT was considered to report on a subset of patients of a larger trial (possible duplicate). Two RCTs enrolled exclusively children, and one RCT compared inpatient versus outpatient preparation in adults. The remaining 39 RCTs were classified into two mutually exclusive groups: trials comparing OMBP versus no OMBP, each with or without enema (active versus inactive comparison) and trials comparing alternative active OMBP strategies (active versus active comparison).

Compared with studies of OMBP versus no OMBP, studies of active OMBP regimens were conducted in earlier years (median year of enrollment start, 1986 vs. 2001) and more often, or even exclusively, employed preparations that have fallen out of use (e.g., several-day-long preparations, multiple enemas, and whole-gut irrigation with large volumes administered through nasogastric tubes). Most importantly, perioperative parenteral antibiotics were used in almost all arms of studies of OMBP versus no OMBP (1 study reported unclear information), compared with only 26 of the 46 OMBP-treated arms. Because of these differences, we considered comparisons of OMBP versus no OMBP separately from comparisons among alternative active OMBP strategies. The former appear to be applicable to contemporary decisionmaking regarding preoperative preparation, whereas the latter are less so.

OMBP Versus No OMBP

Eighteen RCTs and seven NRCSs contributed information to the main analysis. Common indications for surgery were colorectal cancer and diverticular disease. Details on the surgical approach (e.g., operation types, anastomosis methods, open vs. surgical surgery) were generally poorly reported. With respect to stratification by surgical site, one study enrolled exclusively patients undergoing rectal surgery and two studies enrolled only patients undergoing left-sided colorectal surgeries. In total, through author contact and previous reviews, we could obtain results stratified by anatomic location or restricted to a single location from 11 trials for the outcome of anastomotic leakage.

All but two studies enrolled adult patients (or did not provide relevant information). Two RCTs explicitly reported that the study population consisted of both adults and children but did not report results stratified by age group. Because children are probably the minority of the study sample and for consistency with previous work, we included these studies together with studies enrolling exclusively adults. In sensitivity analyses, we assessed the robustness of our results to their removal from the dataset.

RCTs

Eighteen RCTs compared OMBP versus no OMBP. Studies used a variety of OMBP regimens: seven used PEG, five used other laxatives or cathartics, and six used other methods (including combinations of the aforementioned regimens). Almost all studies reported using intravenous antibiotics in the perioperative period (one study provided unclear information) and three studies reported also using oral antibiotics.

The majority of RCTs were considered to be at moderate risk of bias. Overall, based on the number of items considered indicative of "low" risk, eight studies were considered to be at high risk of bias, nine to be at moderate risk of bias, and one to be at low risk of bias.

In order to extract the maximum amount of information from the available RCTs, we used two meta-analytic approaches: (1) a pairwise meta-analysis of trials directly comparing OMBP with either enema or no preparation and (2) a network meta-analysis of the same trials as the basis for calculating the probability that each intervention was best/second best/worst. Both approaches were subjected to extensive sensitivity analyses. We based our assessment of the evidence on the results of all these analyses.

Table A shows pairwise Bayesian random-effects meta-analyses of all RCTs for six clinical outcomes and analyses stratified by whether enema was administered in the comparator group. For all outcomes the 95% credible intervals (CrIs) included an odds ratio (OR) of 1 (i.e., no effect); however, these intervals were wide and did not exclude clinically important differences in either direction. These results were robust to extensive sensitivity analyses. There was some indication of between-study heterogeneity, particularly for the comparison of OMBP with or without enema versus enema, but the CrIs around the between-study variance estimates were very broad.

For outcomes reported by 10 or more studies (all-cause mortality, anastomotic leakage, and wound infection), we also investigated whether the effect of OMBP varied by anatomic location (colon vs. rectum), year of publication, or items related to study risk of bias (specifically, randomized sequence generation and allocation concealment).

Separate analyses by anatomic location were possible only for the outcome of anastomotic leakage. There was no evidence of effect modification by anatomic location; however, summary estimates were imprecise and evidence was available from 10 studies (11 publications) that used heterogeneous subgroup definitions. The OR for anastomotic leakage comparing OMBP versus enema or no preparation was 1.01 (95% CrI, 0.57 to 1.96) for colon surgery (9 studies) and 0.91 (95% CrI, 0.42 to 2.45) for rectal surgery (7 studies, 6 of which provided information for both subgroups).

Regression analyses did not reveal any time trends and suggested that randomized sequence generation methods did not have a major impact on the effect size for all outcomes considered. Similarly, allocation concealment method was not associated with the effect sizes for all-cause mortality or wound infection. CrIs were wide, indicating substantial uncertainty regarding effect modification by these factors. However, trials with adequate and clearly reported allocation concealment methods suggested that OMBP has a protective effect (i.e., OR <1) for anastomotic leakage, whereas trials with inadequate or unclearly reported allocation concealment methods had a summary effect in the opposite direction (i.e., OR >1); the relative OR comparing these results was 0.45 (95% CrI, 0.23 to 0.85). We caution against interpreting this result as "proof" for the presence of bias because—

- The reporting of allocation concealment was incomplete in the reviewed studies. (The adequacy of allocation concealment could not be determined in 10 studies.)
- Other study characteristics that may be associated with allocation concealment methods (and reporting) could not be accounted for in the analysis.
- The association was observed for only one of the outcomes of interest and in one of several regression analyses.
- The relative OR was extreme and fairly imprecise.

Of note, in the subgroup of studies with adequate allocation concealment, the CrI of the OR for anastomotic leakage comparing OMBP versus enema or no preparation included the null value; OR = 0.81 (95% CrI, 0.56 to 1.19). These findings, in conjunction with the wide CrIs observed in the overall meta-analysis, support the need for more research.

Table A. Pairwise meta-analysis results for comparison of OMBP versus enema or no preparation

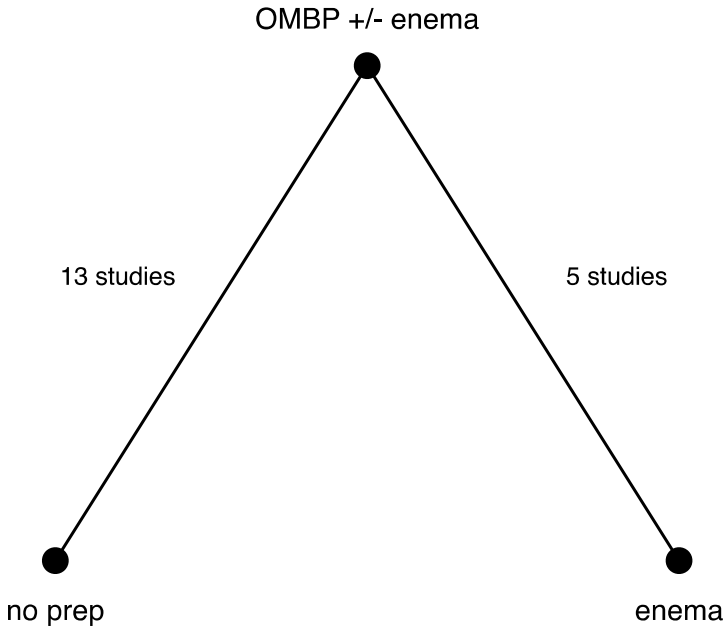
Outcome	Comparison	N Studies (N Events/N Patients Per Group)	OR (95% CrI)	Between-Study Variance (95% CrI)
All-cause mortality	OMBP ± enema vs. enema/no prep	14 (45/2,550 vs. 44/2,544)	1.17 (0.67 to 2.67)	0.12 (0.00 to 1.99)
	OMBP ± enema vs. no prep	10 (38/2,024 vs. 40/2,014)	1.09 (0.57 to 2.99)	0.17 (0.00 to 2.61)
	OMBP ± enema vs. enema	4 (7/526 vs. 4/530)	1.99 (0.27 to 18.45)	0.82 (0.00 to 3.76)
Anastomotic leakage	OMBP ± enema vs. enema/no prep	16 (126/2,702 vs. 124/2,680)	1.08 (0.79 to 1.63)	0.08 (0.00 to 0.72)
	OMBP ± enema vs. no prep	12 (102/2,176 vs. 103/2,150)	1.06 (0.73 to 1.73)	0.09 (0.00 to 0.95)
	OMBP ± enema vs. enema	4 (24/526 vs. 21/530)	1.24 (0.38 to 4.72)	0.61 (0.00 to 3.59)
Wound infection	OMBP ± enema vs. enema/no prep	16 (266/2,612 vs. 239/2,603)	1.19 (0.93 to 1.63)	0.04 (0.00 to 0.41)
	OMBP ± enema vs. no prep	12 (218/2,086 vs. 190/2,073)	1.27 (0.95 to 1.88)	0.05 (0.00 to 0.50)
	OMBP ± enema vs. enema	4 (48/526 vs. 49/530)	1.04 (0.37 to 3.34)	0.52 (0.00 to 3.46)
Peritonitis/ intra-abdominal abscess	OMBP ± enema vs. enema/no prep	14 (51/2,381 vs. 70/2,362)	0.84 (0.50 to 1.66)	0.25 (0.00 to 1.77)
	OMBP ± enema vs. no prep	10 (45/1,855 vs. 64/1,832)	0.84 (0.45 to 2.00)	0.38 (0.00 to 2.74)
	OMBP ± enema vs. enema	4 (6/526 vs. 6/530)	0.99 (0.21 to 4.68)	0.42 (0.00 to 3.51)
Reoperation	OMBP ± enema vs. enema/no prep	8 (124/1,967 vs. 119/1,945)	1.14 (0.57 to 2.65)	0.38 (0.00 to 3.23)
	OMBP ± enema vs. no prep	6 (117/1,742 vs. 111/1,723)	1.15 (0.73 to 2.50)	0.09 (0.00 to 1.82)
	OMBP ± enema vs. enema	2 (7/225 vs. 8/222)	0.50 (0.03 to 6.12)	2.49 (0.27 to 3.93)
SSI	OMBP ± enema vs. enema/no prep	7 (206/1,279 vs. 197/1,230)	1.19 (0.56 to 2.63)	0.64 (0.11 to 2.91)
	OMBP ± enema vs. no prep	5 (173/1,087 vs. 171/1,040)	1.10 (0.41 to 3.05)	0.76 (0.10 to 3.39)
	OMBP ± enema vs. enema	2 (33/192 vs. 26/190)	1.50 (0.24 to 10.42)	1.20 (0.02 to 3.79)

CrI = credible interval; no prep = no OMBP and no enema; OMBP = oral mechanical bowel preparation; OR = odds ratio; SSI = surgical site infection

Note: OR values lower than 1 indicate that events are less common among OMBP-treated groups (i.e., that OMBP is beneficial).

Using network meta-analysis we compared "OMBP with or without enema," "enema," and "no preparation" (Figure A). This analysis "respects" the randomization procedure within each study and allows us to "borrow strength" from all studies in estimating between-study heterogeneity. The point estimates in Table B are similar to those from pairwise meta-analyses (Table A).

Figure A. Three-node network structure



No prep = no OMBP and no enema; OMBP = oral mechanical bowel preparation
Note: Network structure for the 3-node network meta-analysis comparing OMBP +/- enema vs. enema alone vs. no preparation. Nodes indicate the treatments compared. Connecting lines depict direct comparisons and are labeled with the total number of available studies. (Not all studies contributed data for all outcomes.) A total of 18 studies reported information on at least 1 of the outcomes of interest. Some studies did not report information on some outcomes. (This is why the number of studies for each outcome in Table A is not 18.)

Table B. Summary estimates from the three-node network meta-analysis

Outcome	Comparison	OR (95% CrI)
All-cause mortality	OMBP ± enema vs. no prep	1.08 (0.56 to 3.02)
	OMBP ± enema vs. enema	1.88 (0.40 to 10.56)
Anastomotic leakage	OMBP ± enema vs. no prep	1.07 (0.73 to 1.73)
	OMBP ± enema vs. enema	1.20 (0.57 to 2.61)
Wound infection	OMBP ± enema vs. no prep	1.27 (0.94 to 1.91)
	OMBP ± enema vs. enema	1.00 (0.59 to 1.76)
Peritonitis/intra-abdominal abscess	OMBP ± enema vs. no prep	0.82 (0.46 to 1.82)
	OMBP ± enema vs. enema	0.99 (0.24 to 4.07)

CrI = credible interval; no prep = no OMBP and no enema; OMBP = oral mechanical bowel preparation; OR = odds ratio
Note: OR values lower than 1 indicate that events are less common among treatment groups receiving the first-listed treatment for each comparison. Results based on indirect comparisons were very imprecise and are not shown. Outcomes with fewer than 6 studies were not analyzed with network meta-analysis; analyses for reoperation and surgical site infections produced very wide CrIs and are not shown.

Results were robust in all sensitivity analyses: use of informative priors, leave-one-out analyses, analyses assuming a fixed-effects model, and reanalyses after excluding a group of studies. Finally, we separated the "OMBP with or without enema" strategy into "OMBP with enema" and "OMBP without enema" in a second network meta-analysis (a four-node network), but the data were not adequate to draw definitive conclusions due to imprecision.

NRCSs

Seven NRCSs reported information on the comparison of OMBP versus no preparation. Because of heterogeneity in patient selection and outcomes reported, differences in study design,

and concerns regarding risk for residual confounding, we did not perform meta-analysis. In sum, the NRCSs reported results consistent with those of RCTs and did not demonstrate significant differences between OMBP and no-OMBP strategies. At the same time, CrIs were generally broad (e.g., could not exclude a 50% change in odds in either direction). Studies were at substantial risk of bias, mostly due to confounding factors that had not been adequately controlled in the design or analysis of these investigations.

Alternative Active OMBP Strategies

Twenty-three RCTs and two NRCSs provided information on comparisons among active OMBP strategies for patients undergoing elective colorectal surgery. We first examine the findings of RCTs, followed by the findings of NRCSs.

RCTS in Adults

Twenty-one of the 23 RCTs enrolled primarily adult patients and 2 enrolled exclusively children. The most common indications for surgery were colorectal cancer and diverticular disease. Information on the surgical approach (e.g., operation types, anastomosis methods, open versus laparoscopic surgery) and on the breakdown of surgical sites into right colon, left colon, and rectum was generally not reported.

The majority of RCTs (19 out of 23) had 2 treatment groups, 3 had 3 groups, and 1 had 4 groups, for a total of 51 active OMBP groups and 34 possible pairwise contrasts. Studies compared diverse OMBP strategies. We grouped OMBP strategies into seven grand categories to facilitate synthesis and presentation: PEG, PEG combined with laxatives or cathartics, hyperosmotic sodium solutions, other laxatives or cathartics, whole-gut irrigation with electrolyte solutions (other than PEG), mixed/other (e.g., combinations of OMBP drugs), and dietary interventions. The most common comparisons were PEG versus whole-gut irrigation (examined in 5 RCTs) and PEG-based versus laxative/cathartic-based OMBP (5 RCTs).

Many items necessary for detailed assessment of risk of bias were not reported in most studies. Overall, based on the number of items considered indicative of "low" risk, 10 studies were considered to be at high risk of bias, 12 to be at intermediate risk of bias, and 1 to be at low risk of bias.

We did not perform a meta-analysis because of the extensive diversity of the OMBP strategies employed, the heterogeneity in the assessed outcomes, and concerns regarding selective outcome reporting (and other risk-of-bias dimensions). Instead, we summarize the information extracted from studies qualitatively. Briefly, we observed that—

- **Only 13 out of the 28 possible comparisons had some empirical information** (i.e., at least 1 study provided evidence about them). The "density" of observed versus possible comparisons is somewhat optimistic: we were quite lenient in categorizing the individual active OMBP comparisons into the seven broad categories represented by the rows and columns in each panel.
- **Outcomes were assessed or reported in sufficient detail in a minority of the conducted studies**, perhaps with the exception of wound infection. When two or more studies provided information for the same outcome, no conclusions could be reached regarding the comparative effectiveness of interventions.
- **Some of the outcomes of interest to this review, such as surgical site infections, pulmonary embolism, and venous thrombosis, were not reported in any study.** The

empirical evidence that is available to a literature-based review is but a small fraction of what could have been available. This represents a lost opportunity.

- **The majority of available studies were small and probably underpowered to detect modest or small effect sizes, let alone relatively rare harms**. Across all 106 analyzable results (outcome/comparison combinations), 1 was statistically significant.[b] This proportion (2%) is less than the 5 percent that would be expected by chance if the null hypothesis of no association were true. Because the true distribution of effects in this body of literature is unknown and because these analyses are not independent (when results are derived from the same study, analyses are performed in the same patient population), one cannot simply infer that all identified statistically significant findings are false. Nevertheless, this observation is congruent with the notion that very few, if any, genuine differences exist among active OMBP strategies in the included studies.

RCTS in Children

Two studies, both conducted in India, compared alternative active OMBP strategies in children undergoing colorectal surgery. The first study compared whole-gut irrigation with normal saline with added potassium versus PEG. The second study compared whole-gut irrigation with normal saline, PEG, or Ringer's lactate. Both studies were considered to be at high risk of bias and did not provide conclusive evidence on the comparative effectiveness of the OMBP strategies they evaluated.

NRCSs

Only two NRCSs reported information on the comparison of alternative active OMBP strategies, including preparations that are no longer in clinical use (e.g., mannitol). The same observations that apply to the RCTs of alternative active interventions apply here as well.

Inpatient Versus Outpatient OMBP

One RCT and one retrospective NRCS compared inpatient versus outpatient use of OMBP using PEG. Both studies were considered to be at high risk of bias. No statistically significant differences among arms were reported. However, results were inconclusive due to the very small number of events for all reported outcomes.

Harms: OMBP Versus No OMBP or Enema; Different OMBP Strategies (Key Question 2)

To address Key Question 2 we summarize the evidence on the following predefined potential adverse events of OMBP: nausea; vomiting; dehydration; electrolyte imbalance; kidney damage; emergency admissions prior to surgery; canceled, delayed, or rescheduled surgeries; allergic reactions; and seizures. The organization of the subsequent sections follows that of Key Question 1. We first discuss comparative studies of OMBP versus enema or no preparation, followed by comparative and noncomparative (single-group) studies of alternative active OMBP strategies.

[b]These results pertain to the following outcomes: all-cause mortality, cause-specific mortality, anastomotic leakage, wound infection, wound dihiscence, peritonitis/intra-abdominal abscess, surgical site infections, infectious complications (not otherwise specified), extra-abdominal infections, reoperation, pulmonary embolism, and venous thrombosis.

We did not attempt a meta-analysis because of the substantial diversity in outcome definitions, and variation in the reporting of adverse events.

OMBP Versus No OMBP

Of the 18 RCTs included in our main analyses comparing OMBP with or without enema versus enema alone or no preparation, only two provided information on harms (1 for nausea and 1 for renal failure). In the study reporting data on nausea, 9 out of 95 OMBP-treated patients and 8 of 90 controls reported experiencing nausea ($p = 0.77$). In the other study, 3 of 89 patients receiving OMBP versus 1 of 89 patients receiving no preparation experienced acute renal failure ($p = 0.62$). None of the seven NRCSs comparing OMBP versus no preparation reported information on the prespecified adverse events.

Alternative Active OMBP Strategies

RCTs in Adults

As discussed in the corresponding section of Key Question 1, studies of alternative active OMBP strategies used diverse OMBP strategies, assessed heterogeneous outcomes, and, raised concerns of selective outcome reporting (and other risk-of-bias dimensions). Regarding the assessment of adverse events, studies utilized a diverse set of symptom scales to measure severity of patient-reported adverse events (nausea, vomiting, fatigue, bloating, cramping, etc.). In most studies adverse event definitions were not clearly described, making it impossible to consistently compare outcomes across studies. For these reasons, we have used the same approach as in Key Question 1 and summarize findings qualitatively.

We make observations similar to those for Key Question 1: empirical information is available only for some out of many possible contrasts, and when provided, it is poorly reported. For example, most reported data fall into the outcome category “other patient-reported adverse events,” which is indicative of nonstandardized reporting. Renal failure, an outcome considered important given that many OMBP strategies involve ingestion of large volumes of electrolyte solutions, was not reported in any study. Further, the majority of the available studies were small and probably underpowered to detect modest or small effect sizes, let alone relatively rare harms. Across all 88 analyzable results (outcome/comparison combinations), 27 were statistically significant. However, there is no readily discernible pattern. Because the true distribution of effects in this body of literature is unknown and because many of these analyses are not independent (e.g., nausea often accompanies vomiting), one cannot make statements on whether the identified statistically significant findings are more than what would be expected by chance.

RCTs in Children

The studies comparing alternative active OMBP strategies in children undergoing colorectal surgery did not provide conclusive evidence on the adverse events of the OMBP strategies they evaluated.

NRCSs

The two NRCSs comparing alternative active OMBP strategies versus no preparation did not report information on the prespecified adverse events.

Single-Group Cohorts

Six studies met our inclusion criteria for single-group cohorts and reported results on at least one of the prespecified adverse events. Overall, reporting of adverse events was partial and was limited to vomiting, nausea, vomiting and nausea, and allergic reactions. Almost universally, the rates of reported adverse events were below 4 percent. The exception was a cohort of patients receiving OMBP with sodium phosphate with or without oral antibiotics, for whom the rate of vomiting was approximately 17 percent (51 of 300 patients). No study made causal attributions of the adverse events to the OMBP drugs or to the cointerventions. No studies reported adverse events by any of the prespecified subgroups of interest.

Inpatient Versus Outpatient OMBP

The two studies (1 RCT and 1 NRCS) comparing inpatient versus outpatient administration of OMBP did not report information on the prespecified adverse events of interest.

Discussion

Key Findings

We reviewed 60 studies spanning 40 years of empirical research on the benefits and harms of alternative OMBP strategies for elective colorectal surgery and noted a striking shift in the design and focus of research over time. In the early 1970s OMBP was widely considered highly desirable on the basis of pathophysiological arguments, and the majority of research focused on determining which OMBP strategy was best.[5] It appears that those earlier assumptions are being questioned by an increasing number of studies comparing OMBP with no OMBP, while few recent studies compare alternative active OMBP strategies. It is probably fair to state that the most relevant question is whether or not to use OMBP with any of the relatively short-duration preparation regimens that are used in current practice.

After examining the literature for a wide range of clinical outcomes, we found no evidence that OMBP with or without enema differs from enema or no preparation. However, the uncertainty accompanying the estimated treatment effects was considerable. Based on the boundaries of the credible intervals, one cannot exclude a modest (e.g., 30–50%) change in odds in either direction for all-cause mortality, anastomotic leakage, wound infection, and peritonitis. This uncertainty is explained by the relatively small sample size of included studies and the relative rarity of key clinical events such as death, anastomotic leakage, reoperation, and severe infection. Of more concern, information on important subgroups, such as by anatomic location (colon vs. rectum) and type of surgery (laparoscopic vs. open), was sparsely reported in the published literature, as was information on important potential effect modifiers (e.g., oral or parenteral antibiotics). We also attempted to assess the comparative effectiveness of different OMBP strategies, but the studies were too small and heterogeneous for firm conclusions, and in any case most of the strategies compared are no longer in use, rendering the results nonapplicable. Similarly, we attempted to assess harms, but too few studies collected harms consistently.

Assessment of the Strength of Evidence

Table C presents a summary of the report's key findings for each Key Question. When appropriate, results are presented separately for each of the populations and outcomes of interest.

Please see the Methods section of the full report for a detailed discussion of our approach to rating the strength of evidence. Overall, we found weak evidence that OMBP and no preparation had similar effectiveness with respect to the outcomes of all-cause mortality, anastomotic leakage, wound infection, and peritonitis. The ORs for these outcomes were all close to 1 and the CrIs from pairwise meta-analyses excluded large differences (e.g., increasing the odds of an outcome by 2-3 times). For all other outcomes for this comparison, results were too imprecise to exclude even larger treatment effects and thus insufficient to draw conclusions. Similarly, we found that evidence on the comparison of OMBP versus enema was insufficient for all outcomes of interest.

Table C. Summary assessment of the strength of evidence

Population	Outcome	Comparison	Assessment of Strength of Evidence	Key Findings and Comments*
KQ1: Adult patients undergoing colorectal surgery	All-cause mortality	OMBP vs. no prep	Low (for lack of difference)	The OR in meta-analysis of 10 studies was 1.09 (95% CrI, 0.57 to 2.99), indicating moderate to substantial uncertainty in the summary estimate. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
		OMBP vs. enema	Insufficient	The OR in meta-analysis of 4 studies was 1.99 (95% CrI, 0.27 to 18.45), indicating substantial uncertainty in the summary estimate. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
	Anastomotic leakage	OMBP vs. no prep	Low (for lack of difference)	The OR in meta-analysis of 12 studies was 1.06 (95% CrI, 0.73 to 1.73), indicating moderate uncertainty in the summary estimate. Pairwise analysis concurred. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
		OMBP vs. enema	Insufficient	The OR in meta-analysis of 4 studies was 1.24 (95% CrI, 0.38 to 4.72), indicating substantial uncertainty in the summary estimate. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
	Wound infection	OMBP vs. no prep	Low (for lack of difference)	The OR in meta-analysis of 12 studies was 1.27 (95% CrI, 0.95 to 1.88), indicating moderate uncertainty in the summary estimate. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.

Table C. Summary assessment of the strength of evidence (continued)

Population	Outcome	Comparison	Assessment of Strength of Evidence	Key Findings and Comments*
KQ1: Adult patients undergoing colorectal surgery (continued)		OMBP vs. enema	Insufficient	The OR in meta-analysis of 4 studies was 1.04 (95% CrI, 0.37 to 3.34), indicating substantial uncertainty in the summary estimate. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
	Peritonitis/intra-abdominal infection	OMBP vs. no prep	Low (for lack of difference)	The OR in meta-analysis of 10 studies was 0.84 (95% CrI, 0.45 to 2.00), indicating moderate uncertainty in the summary estimate. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
		OMBP vs. enema	Insufficient	The OR in meta-analysis of 4 studies was 0.99 (95% CrI, 0.21 to 4.68), indicating substantial uncertainty in the summary estimate. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
	Reoperation	OMBP vs. no prep	Insufficient	The OR in meta-analysis of 6 studies was 1.15 (95% CrI, 0.73 to 2.50), indicating substantial uncertainty in the summary estimate. Studies were at moderate ROB. There was some concern regarding selective outcome reporting. There was statistical evidence of inconsistency. However, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected; the 2.5th percentile of the posterior distribution of the between-study variance of the log-OR was 0.27.
		OMBP vs. enema	Insufficient	The OR in meta-analysis of 2 studies was 0.50 (95% CrI, 0.03 to 6.12), indicating substantial uncertainty in the summary estimate. Studies were at moderate ROB. There was some concern regarding selective outcome reporting. There was statistical evidence of inconsistency; however, estimates were imprecise.

Table C. Summary assessment of the strength of evidence (continued)

Population	Outcome	Comparison	Assessment of Strength of Evidence	Key Findings and Comments*
KQ1: Adult patients undergoing colorectal surgery (continued)	All other effectiveness outcomes	OMBP vs. no prep	Insufficient	Few if any studies reported information; study-specific results were imprecise. There was concern about selective outcome reporting.
		OMBP vs. enema	Insufficient	Few if any studies reported information; study-specific results were imprecise. There was concern about selective outcome reporting.
	All outcomes	Alternative active OMBP strategies vs. each other	Insufficient	Individual studies compared diverse interventions and reported outcomes heterogeneously, precluding synthesis. Study-specific results were imprecise. Studies were at moderate to high ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
		Inpatient vs. outpatient OMBP	Insufficient	Only 2 studies were available (1 RCT at moderate ROB and 1 NRCS at high ROB). Study-specific estimates were imprecise.
KQ1: Children undergoing elective colorectal surgery	All outcomes	All comparisons	Insufficient	Only 2 studies provided evidence on children undergoing elective colorectal surgery. Studies reported information only for wound infection (no other effectiveness outcomes were assessed) and produced imprecise results.
KQ1: Patients undergoing elective surgery for right-sided or left-sided colon, or rectal surgery	All outcomes	All comparisons	Insufficient	Only a minority of studies provided anatomic-location–specific results (and only for anastomotic leakage). Subgroup analyses did not reveal a difference in the effect of OMBP compared with enema or no preparation between colon and rectal surgery population with respect to the outcome of anastomotic leakage. Results were very imprecise for both subgroups and anatomic location was heterogeneously defined across studies. There is concern regarding selective analysis reporting.
KQ2: Patients undergoing elective colorectal surgery (general surgical population)	Adverse events	All comparisons	Insufficient	When interpreting the data available for this review, results are insufficient. Most prespecified adverse events of interest were evaluated by a small minority of studies or not examined at all. When reported, study-specific results did not lead to definitive conclusions due to imprecise results and lack of validation of the measurement scales used (for patient symptom scores). However, the evolution of the preparation strategies used in trials (with most recent studies using PEG-based strategies, possibly in combination with laxatives) indicates that these preparations may be considered the safest or more palatable for patients.

Table C. Summary assessment of the strength of evidence (continued)

Population	Outcome	Comparison	Assessment of Strength of Evidence	Key Findings and Comments*
KQ2: Patients undergoing elective surgery who may be at particular risk for adverse events	Adverse events	All comparisons	Insufficient	No relevant studies were identified.

CrI = credible interval; KQ = Key Question; no prep = no OMBP and no enema; NRCS = nonrandomized comparative study; OMBP = oral mechanical bowel preparation; OR = odds ratio; PEG = polyethylene glycol; RCT = randomized controlled trial; ROB = risk of bias

*Summary estimates reported in this table are from the pairwise Bayesian meta-analysis. Results from extensive sensitivity analyses and network meta-analyses were consistent with those presented in the table.

Compared with the most recent Cochrane Review of OMBP,[1] we included a broader spectrum of study designs (including NRCSs and single-group cohorts) and performed more extensive data analyses using Bayesian network meta-analysis. Furthermore, we identified several studies published after the last search of the Cochrane Review and excluded from main analyses (and subjected to sensitivity analyses) a recently retracted study that had been included in the Cochrane Review. As a result of using analyses that more fully account for the uncertainties in the synthesis of evidence, our interpretation of the evidence base is more conservative than that of the Cochrane Review and other recent meta-analyses.[1,25-28] While, like those reviews, we did not find evidence of clear benefit from OMBP, the wider CrIs around our results lead us to conclude that modest benefit or harm cannot be excluded. Given the very large number of colorectal surgeries performed annually, modest effects can be clinically significant, and therefore further research is urgently needed to provide a definitive answer. Furthermore, there are a number of potentially important factors that could modify the effect of OMBP (e.g., coadministration of oral antibiotics, type of surgery, location of surgery), which existing studies do not adequately address. Therefore we believe that additional studies are needed to assess the comparative effectiveness of alternative OMBP strategies.

Limitations of This Review

Several limitations need to be considered when interpreting our results. First, our conclusions, to a large extent, reflect weaknesses of the underlying evidence base. For example, our ability to perform important subgroup analyses to explore the impact of patient-, disease-, or system-level characteristics on the effectiveness of OMBP is limited by the incomplete reporting of relevant information in the published papers. Second, we excluded studies not published in English, although this is unlikely to cause major bias, since previous work identified only four relevant non–English-language publications including a total of 269 patients. Third, we relied mainly on electronic database searches and perusal of reference lists to identify relevant studies. Unpublished relevant studies may have been missed. Fourth, indexing of nonrandomized studies, and single-group cohort studies in particular, is less complete than indexing of randomized trials and we may have failed to identify relevant studies. However, in order to increase the sensitivity of our searches, we did not use search filters that limit results to specific study designs.

Applicability

The existing evidence base comparing OMBP, with or without enema, versus enema or no preparation appears to be applicable to U.S. settings. Studies enrolled patients with an age distribution similar to that of patients undergoing colorectal surgery in the United States and for indications that represent the most prevalent indications in U.S. clinical practice. However, none of these studies was conducted in the United States, raising the possibility that system-level differences (e.g., differences in policies on oral antibiotics, preoperative fluid use, or fasting) may render findings less applicable to U.S. surgical practice. Findings may be most applicable to patients undergoing colon surgery; data on patients undergoing rectal surgery were sparse, and thus the applicability of findings to this population is at best unclear. Similarly, the applicability of our findings to patients undergoing laparoscopic colorectal surgery is unclear because few studies reported relevant information. Regarding studies comparing alternative active OMBP strategies, applicability appears to be severely limited because they examined OMBP regimens that have fallen out of use in modern practice, such as whole-gut irrigation with non-PEG electrolyte solutions and mannitol.

Limitations of the Evidence

On the basis of the reviewed studies, we believe that the evidence regarding OMBP for colorectal surgery is limited in the following ways:

- Most studies enrolled small numbers of patients and reported low event rates for major clinical events during followup.
- Studies did not report results for important clinical subgroups, particularly those defined by anatomic location of surgery (colon vs. rectal surgery) and type of surgical procedure performed (e.g., open vs. laparoscopic surgery).
- Studies did not consistently report information on potential effect modifiers (particularly the coadministration of oral antibiotics).
- The literature comparing alternative active OMBP strategies for colorectal surgery was fragmented because studies used a large number of diverse preparation regimens and reported results for heterogeneous, often poorly defined, outcomes.
- Nonrandomized trials, and particularly observational studies, could not effectively supplement the results of randomized trials because of shortcomings in their analysis.

Evidence Gaps

Given the uncertainty of the evidence base, evidence gaps exist for all the Key Questions addressed in this review. In addition, there is particularly limited and incomplete information on those undergoing elective rectal surgery or laparoscopic surgery. The examined literature provided only limited information for key adverse events of interest, and none on whether the adverse events associated with OMBP use are more common in frail patients and patients with very compromised function of major systems (e.g., cardiac, pulmonary, renal, immune).

Ongoing Research

A search on May 15, 2013, in the ClinicalTrials.gov registry identified five records of studies that are expected to provide information relevant to the Key Questions of this report. They may provide more data on OMBP for laparoscopic surgery and rectal surgery, OMBP versus enema, and comparisons among alternative OMBP strategies. Additional trials will be needed to answer all the questions that remain.

Future Research

Although we found no evidence that using OMBP improves outcomes, the evidence base was too weak to confidently exclude either modest benefit or modest harm. Because elective colorectal surgery is a common procedure, even a modest treatment effect would affect a significant number of patients. Therefore, further research is important to verify or rule out any such effect.

We believe that there is need for a large, pragmatic, and definitive RCT examining all combinations of using versus not using OMBP, oral antibiotics, and enema prior to colorectal surgery. Such a study should be feasible in the U.S. setting, given that a large volume of procedures are performed annually, the interventions to be tested are low cost (or already part of standard care), and only short followup is needed. A noninferiority design could be used to explore whether omission of OMBP does not worsen outcomes. Given the increasing interest in reevaluating the role of oral antibiotics in colorectal surgery preparation (especially when OMBP

is omitted), factorial designs could efficiently evaluate both main effects (i.e., OMBP vs. no OMBP, oral antibiotics vs. no antibiotics) and treatment-by-treatment interactions. It is important to collect data according to anatomic location and type of surgery (open vs. laparoscopic).

An individual patient data meta-analysis of existing trials of OMBP (specifically, recent trials of OMBP vs. enema or no preparation) is a lower cost alternative for obtaining information on important subgroups, but it would likely not succeed in reducing the uncertainty around the effectiveness of OMBP. Its results could be used to inform the design of future primary trials. Finally, observational studies can inform the comparative effectiveness of alternative OMBP strategies, particularly for susceptible groups that have not been represented in the RCTs thus far. Such studies should have large sample sizes (to account for the low incidence of most outcome events) chosen on the basis of prospective power analyses, include patients representative of those seen in clinical practice, and use strong methods to address confounding bias (e.g., propensity score or instrumental variable methods). Further, exposure assessment should include the collection of details regarding the preparation strategy (i.e., the OMBP regimen and any cointerventions), and outcome ascertainment should be done using standardized definitions for all outcomes of interest. Although the use of observational data always requires additional assumptions for valid inference on treatment effects (compared with randomized designs), well-designed observational studies can offer valuable information regarding both the effectiveness and adverse effects of OMBP.

Conclusions

We found weak evidence suggesting that OMBP has similar effectiveness as no preparation with respect to all-cause mortality, anastomotic leakage, wound infection, and peritonitis for patients undergoing elective surgery for colorectal cancer. However, the evidence base was too weak to confidently exclude either modest (30–50%) benefit or modest harm. Evidence on the comparative effectiveness of OMBP versus no preparation was insufficient for all other outcomes, as was evidence on the comparative effectiveness of OMBP versus enema for all outcomes. The body of literature on alternative active OMBP strategies was largely irrelevant to current surgical decisionmaking because the trials were underpowered, reported poorly defined outcomes, and compared preparations no longer in use. Future studies, including pooled reanalyses of existing data and new comparative studies (both randomized and nonrandomized), hold promise for informing clinical decisions.

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Background

Oral Mechanical Preparation for Colorectal Surgery

In the U.S. oral mechanical bowel preparation (OMBP), defined as an oral preparation given prior to surgery to clear fecal material from the bowel lumen, is often prescribed preoperatively for patients undergoing elective colorectal surgery.[1] OMBP is sometimes used as a precaution in anticipation of possible iatrogenic bowel injury during abdominal and pelvic surgeries that do not entail resection of the colon or rectum (e.g., urologic or gynecologic procedures). OMBP is also routinely prescribed prior to colonoscopy, to allow maximal visualization of the intraluminal bowel during the procedure, although that use is not within the scope of this report.

In 2009 there were 254,000 surgeries categorized as partial excisions of the large intestine;[2] of these, 99.2 percent were for patients 15 years of age or older, and 50.4 percent were for patients 65 years of age or older. An analysis of claims from one large insurer demonstrated that the most common indication for colorectal surgery was cancer (43.9 percent), followed by diverticulitis (30.4 percent), and inflammatory bowel disease (4.5 percent).[3]

In the context of colorectal surgery, many have considered OMBP necessary to prevent infectious complications, mainly based on the belief that postoperative infectious morbidities are related to spillage of septic bowel contents during surgery and anastomotic leakage immediately after surgery.[4] Gross spillage of fecal material in the operative field increases the need for a stoma, which can impact patients' quality of life. Moreover, a stoma requires additional surgery (to reverse it), and possibly other surgeries should complications such as bowel obstructions or incisional hernia arise.[5,6] Complication rates for elective colorectal surgery range between 4 and 36 percent.[7,8] A surgical site infection can increase the hospitalization stay from approximately 4 to 21 days and increase costs from approximately $11,000 to $43,000.[7] A recent analysis of more than 10,000 patients from a commercial insurance database reported that the 90-day readmission rate was 23.3 percent and the 30-day surgical site infection rate was 18.8 percent, following colorectal surgery.[3] The median cost of a surgical site infection readmission was $12,835.

OMBP for colon or rectal surgery appears to be widespread practice in the United States. A 2003 U.S. survey showed that more than 99 percent of colorectal surgeons routinely employed OMBP.[9] A recent study (2007–2009) of 24 Michigan hospitals reported that 86 percent of all elective colorectal surgeries were preceded by OMBP (49.6 percent without oral antibiotics and 36.4 percent with oral antibiotics).[10] In addition, anecdotal data from a recent meeting of the American Society of Colon and Rectal Surgeons indicated that OMBP use is widespread in the U.S. although recent surveys indicate that some surgeons have discontinued use of OMBP for right-side colon surgery.

The initial adoption of OMBP prior to colorectal surgery was based on expert opinion and observational data.[11,12] Recently, several trials (mostly conducted in Europe) found no statistically significant benefit for OMBP with colon surgery. For example, a recent large randomized trial found that the rate of anastomotic leakage, wound infections, and mortality did not differ by more than 3% between patients assigned to OMBP as compared to those assigned to the control group. On the basis of these data, utilization of OMBP has declined in Europe, but less so in the U.S.[13]

Clinical guidelines reflect this uncertainty. For example, the 2010 guidelines of the Canadian Society of Colon and Rectal Surgeons stated that good evidence supported the omission of OMBP in the preoperative management of patients undergoing open elective right-sided and left-sided colorectal surgical resections.[14] However, the guidelines also stated that there was

insufficient evidence to support or refute the omission of OMBP for patients undergoing low anterior resection (with or without diverting stomas) or for patients undergoing laparoscopic colorectal surgery. The evidence regarding the use of enemas was also considered insufficient.

Clinical Use of OMBP Regimens

In the U.S. commonly used OMBP agents are approved by the U.S. Food and Drug Administration and are available over the counter. OMBP regimens in clinical use differ with respect to their mechanism of action, volume of preparation that needs to be ingested, and duration of use. The most commonly used oral laxative agents currently are over-the-counter, large-volume, osmotically balanced polyethylene glycol (PEG) solutions (e.g., MiraLAX®, GoLYTELY®, NuLYTELY®) or reduced-volume PEG with the addition of bisacodyl (HalfLytely®). PEG solutions evacuate the bowel by washout of ingested fluid (approximately 4 liters), with no substantial fluid or electrolyte shifts.[7] Bisacodyl, a poorly absorbed diphenylmethane, stimulates colonic peristalsis and requires a smaller volume of ingested fluid (approximately 2 liters).[15] Hyperosmotic preparations (e.g., Fleet®) that draw water into the bowel to achieve washout are less used because of concern about electrolyte imbalances.[15]

Typically, the patient starts the OMBP at home the day before surgery. Elderly and frail patients may undergo OMBP in the hospital. Patients dislike the large quantities of unpleasant-tasting laxative solutions required and the long time spent on the toilet. A minority of patients requires medical attention for vomiting, dehydration, and other reactions to OMBP; this may require cancellation and rescheduling of surgery. Additionally, liquid bowel contents from OMBP use may be less safely handled during surgery than solid contents and may represent a source of infection. Individuals who may be at greater risk of adverse effects of OMBP are the elderly (for example, ≥65 years of age) and those with comorbidities such as cardiovascular and pulmonary disease, diabetes, kidney disease, and compromised immune conditions.

Cointerventions

Evaluation of the effectiveness of OMBP needs to take into account the effects of cointerventions, such as enemas or antibiotics, on clinical outcomes. An enema is sometimes given the night before or the morning of surgery. Oral or intravenous antibiotics are also often administered in preparation for surgery. Mechanical cleansing of the large intestine decreases the total volume of stool in the colon but does not change the concentration of bacteria.[16] For this reason, in addition to the intravenous antibiotics routinely given immediately before and during colorectal surgery, some surgeons also prescribe oral antibiotics.[17] A common oral antibiotic regimen (Nichols-Condon) consists of neomycin and erythromycin given the day before surgery.[18] Metronidazole is often substituted for erythromycin because of its increased effectiveness against anaerobic organisms in the gut. Differences in antibiotic regimens between trials may confound comparisons of postoperative infection rates among trials that otherwise have similar preoperative preparation regimens. Decreased infection rates have been reported when oral antibiotics are added to intravenous antibiotics and OMBP,[10,17] and it was conjectured that oral antibiotics may be more effective when the burden of colonic bacteria has been reduced by means of OMBP.[17]

Current Uncertainties Regarding OMBP

A recent Cochrane systematic review (covering studies up to December 1, 2010) found no benefit for OMBP in terms of anastomotic leaks, other surgical complications, or mortality for mixed populations of patients undergoing colon or rectal resection.[1] Several studies have been published since the last search of the Cochrane review, suggesting that an updated synthesis is needed. Furthermore, large variation in practice exists in different parts of the world, perhaps suggesting that existing syntheses of the evidence do not adequately address all decisionmaking uncertainties.[19,20] Specifically, current reviews do not adequately examine the comparative effectiveness of all feasible alternative bowel preparation strategies and have relied on pairwise comparisons between interventions, often lumping different OMBP methods or combining control groups who receive no intervention with groups using enemas. This approach may introduce heterogeneity (if alternative OMBP methods have different effectiveness or if enemas are superior to no intervention) and is not helpful in identifying the most effective OMBP approach. By contrast, a joint synthesis of data on all relevant treatment options, including direct comparisons between alternative OMBP strategies, could provide information on which treatment is most effective.

Scope of This Review

The purpose of this review was to systematically evaluate experimental and observational evidence on the benefits and harms associated with the use of OMBP in patients undergoing elective colorectal surgery. We also aimed to identify patient and procedural characteristics that modify the effect of OMBP on outcomes.

Key Questions

On the basis of the original topic nomination and an extensive process of topic development and refinement, we formulated the following Key Questions to guide the review:

Key Question 1: How do various preoperative OMBP strategies compare between them and versus a control with respect to their effectiveness for preventing surgical or postsurgical complications?

a. For elective *right colon* surgery?
b. For elective *left colon* surgery?
c. For elective rectal surgery?

Key Question 2: How does the use of OMBP, with or without cointerventions (e.g., antibiotics, rectal enema), compare with no OMBP or with OMBP plus different cointerventions with respect to presurgical and postsurgical adverse events?

a. What are the comparative adverse events of the various OMBP strategies?
b. What are the comparative adverse events of OMBP in subgroups of patients especially susceptible to the potential adverse events?

Methods

This comparative effectiveness review evaluated the impact of alternative oral mechanical bowel preparation (OMBP) strategies for patients undergoing elective colorectal surgery. We considered comparisons between use of OMBP and its omission, as well as comparisons among alternative OMBP strategies.

We performed a systematic review of the published literature using established methodologies as outlined in the Agency for Healthcare Research and Quality (AHRQ) "Methods Guide for Effectiveness and Comparative Effectiveness Reviews" (hereafter referred to as the Methods Guide[a]). The main sections in this chapter reflect the elements of the protocol established for the comparative effectiveness review. We followed the reporting requirements listed in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.[21] All methods and analyses were determined a priori. The protocol was developed with input from external clinical and methodological experts and in consultation with the AHRQ task order officer (TOO); it was posted online to solicit additional public comments. Its PROSPERO registration number is CRD42013004381.

AHRQ Task Order Officer

The AHRQ TOO assigned to this project was responsible for overseeing all aspects of this report. The TOO facilitated a common understanding among all parties involved in the project, resolved ambiguities, and fielded all queries from the Evidence-based Practice Center (EPC) regarding the scope and processes of the project. The TOO and other staff at AHRQ reviewed the report for consistency, clarity, and to ensure that it conforms to AHRQ standards.

External Stakeholder Input

An initial set of questions for evidence review were nominated to the Effective Healthcare Program by a representative of a professional society. During a topic refinement phase, the initial questions that had previously been nominated for this report were refined with input from a panel of Key Informants representing clinicians, patients, and payers. After a public review of the proposed Key Questions, a group of experts was convened to form the Technical Expert Panel (TEP), which provided input to help the EPC team identify important issues and to define parameters for the review of evidence. TEP members included representatives of professional societies, experts in colorectal surgery, experts on the preoperative preparation of patients undergoing elective surgery, and an infectious disease specialist. Several TEP members had methodological expertise in health technology assessment.

Key Questions

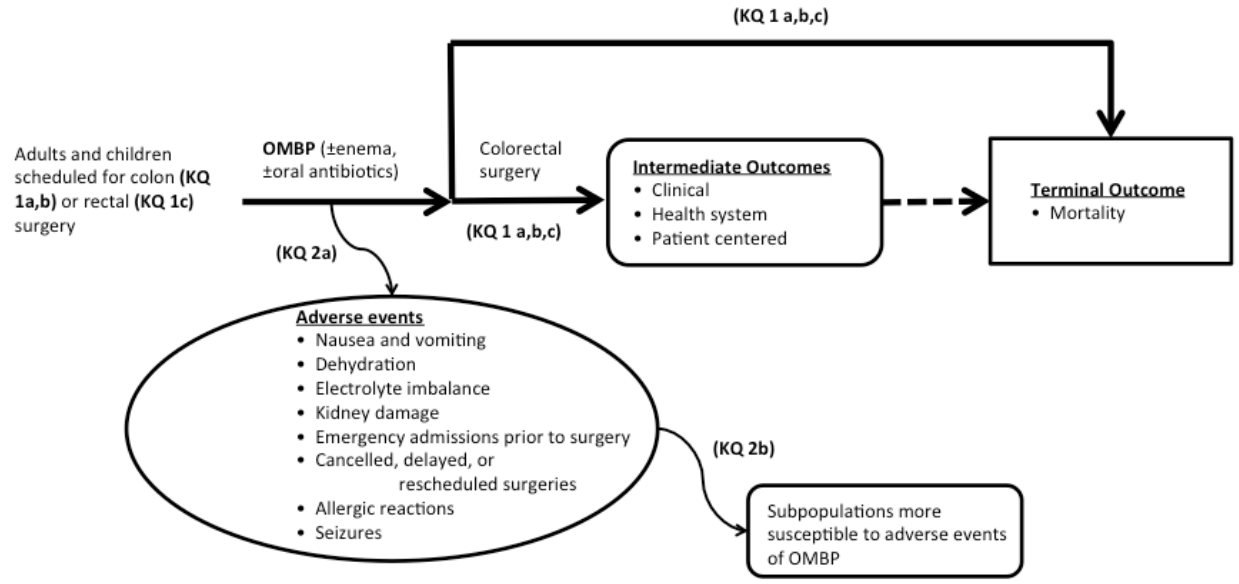
Two Key Questions were posed. Key Question 1 pertained to the comparative effectiveness of alternative OMBP strategies, including a strategy of no preparation. Key Question 2 pertained to adverse events of alternative OMBP strategies, including a strategy of no preparation. The complete Key Questions have been presented at the end of the Introduction section.

[a]Available at www.effectivehealthcare.ahrq.gov/methodsguide.cfm; last accessed May 11, 2013.

Analytic Framework

We developed an analytic framework (Figure 1) that maps the Key Questions within the context of populations, interventions, comparators, and outcomes of interest, as well as the chain of logic that evidence must support to link the interventions to health outcomes. Briefly, the framework illustrates that OMBP, together with various cointerventions (e.g., enemas, oral or intravenous antibiotics, nutritional modifications), can impact intermediate and terminal outcomes (e.g., surgical site infections, anastomotic leakage, mortality), and can also be associated with adverse events (e.g., nausea and vomiting, electrolyte imbalance).

Figure 1. Analytic framework



KQ = Key Question; OMBP = oral mechanical bowel preparation
Note: Key Questions are shown within the context of the PICO (**P**opulation, **I**ntervention, **C**omparators, and **O**utcomes) formalism. Interventions (alternative OMBP strategies or no OMBP) are compared in relevant clinical populations (patients undergoing elective large bowel surgery) with regard to intermediate outcomes (e.g., anastomotic leakage, reoperation, costs, etc.), final outcomes (mortality), or adverse events (e.g., nausea, vomiting, etc.). The intervention effect may be modified by several patient-level factors (e.g., cointerventions, anatomic location of the surgery, use of antibiotics, etc.). See the preceding section for a detailed description of the populations, interventions, and outcomes of interest.

Literature Search and Abstract Screening

We searched PubMed®, the Cochrane Central Trials Registry®, Embase®, and CINAHL® without any language or publication date restriction to identify literature relevant to the report. Searches were conducted on September 6, 2013. Search strings included terms for the populations and treatments of interest (see Appendix A for the exact search queries, which were extensively validated against previous reviews on the treatments of interest). We also performed a targeted search of the FDA Web site (last search performed on May 17, 2013).

To supplement searches, we asked technical experts to provide additional citations of potentially relevant articles. We identified additional studies by perusing reference lists of eligible studies, published clinical practice guidelines, and relevant narrative and systematic reviews. On the basis of preliminary searches conducted during topic refinement, we provided the Scientific Resource Center (SRC, an entity within the Effective Health Care Program

unrelated to the Brown EPC) with a list of relevant technologies and manufacturers. Per EPC procedures, the SRC solicits information from the manufacturers and organizes all obtained material into submission information packages (SIPs). However, as of May 17, 2013 no documents were sent to the SRC from outside sources. All articles identified through sources other than electronic database searches were reviewed for eligibility in full text, using the same criteria as for articles identified through our database searches. Finally, we searched the ClinicalTrials.gov Web site (with the last search performed on May 15, 2013) for ongoing comparative trials of alternative OMBP strategies. We did not consider unpublished data other than the information included in the FDA documents or ClinicalTrials.gov.

Three investigators first screened a common set of 200 abstracts and discussed discrepancies in order to standardize screening practices and ensure understanding of the criteria. The same investigators screened 200 additional abstracts to ensure that selection criteria had been standardized. Remaining abstracts were screened in duplicate and discrepancies were resolved by consensus. Abstracts were manually screened, using *Abstrackr*.[22] Reviewers aimed to be inclusive in order to increase the sensitivity of abstract screening.

Study Selection and Eligibility Criteria

Full-text articles were reviewed independently by two investigators to determine eligibility. Disagreements regarding inclusion or relevance to a specific question were resolved by consensus including at least one additional investigator. Below we detail the study selection criteria for each Key Question.

We did not include studies in languages other than English but we recorded the number of such studies. We excluded narrative reviews, editorials, letters to the editor, and other papers not presenting primary research data. We also excluded studies reporting exclusively on healthy individuals or studies reporting exclusively the results of animal experiments. Appendix B lists all the studies excluded after full-text screening and the reason for exclusion.

Populations and Conditions of Interest

For Key Question 1 the population of interest was adults and children who underwent elective colon (Key Questions 1a and 1b) or rectal surgery (Key Question 1c). Subgroups of interest were those defined by anastomosis location and type (e.g., based on the bowel segments anastomosed or the method of anastomosis, hand-sewn versus stapled), type of surgical procedure (open versus laparoscopic), patient age (children versus adults), and indications for surgery (cancer versus inflammatory bowel disease versus diverticulitis versus other).

For Key Question 2a the population of interest was adults and children who undergo elective colon or rectal surgery. Key Question 2b focused specifically on adverse events in susceptible patient groups undergoing elective colorectal surgery, including adults and children with cardiovascular or pulmonary disease, those at the extremes of age (young children and the elderly), patients who have undergone adjuvant chemotherapy or radiotherapy, and patients with diabetes, kidney disease, or compromised immune function (including drug-induced immunosuppression).

We considered out of the scope of this review studies of patients receiving OMBP in preparation for endoscopic procedures or studies in patients who presented with complete bowel obstruction requiring surgical or endoscopic intervention to initiate OMBP. We also excluded studies of patients undergoing emergency colorectal surgery, and studies reporting results on the use of OMBP on patients undergoing noncolorectal surgery or on mixed populations in which

less than 80 percent of patients underwent colorectal surgery (unless data on the subgroup undergoing colorectal surgery were reported separately).

Interventions

For all Key Questions, the intervention of interest was OMBP administered before colon or rectal surgery. Studies in which the preparation was administered via nasogastric tube were also considered eligible. Mechanical bowel preparation delivered through other routes (e.g., retrograde preparation) was not considered within the scope of the review.

We considered the following cointerventions to be of interest when administered along with OMBP: oral or intravenous antibiotics administered before surgery (e.g., neomycin, erythromycin, metronidazole, various cephalosporins), rectal enemas, and dietary modification in preparation for surgery.

Comparators

We considered alternative OMBP strategies (with or without cointerventions), including a strategy of not using OMBP as the comparators of interest.

Outcomes

For Key Question 1 we considered the following intermediate outcomes: **clinical outcomes** (infectious outcomes [whenever possible, these were classified according to the definitions proposed by the Centers for Disease Control and Prevention[b]], anastomotic leakage, planned and unplanned ostomies, failed attempts to restore bowel continuity, venous thromboembolism [deep venous thrombosis and pulmonary embolism]); **health system and resource utilization outcomes** (readmissions after surgery, reoperation, additional interventional procedures [endoscopy, interventional radiology], length of stay [postoperative and overall], admission to intensive care unit, admission to nursing care); and **patient-centered outcomes** (patient satisfaction, and quality of life). We also extracted data on mortality, which was considered the terminal clinical outcome of interest (including all-cause and cause specific mortality). In general, we adopted the outcome definitions used in the primary studies that we reviewed (when available). For example, we operationally defined peritonitis/ intra-abdominal abscess (an infectious outcome of interest) as the presence of localized (abscess) or non-localized infection in the abdominal cavity. For this outcome, we included data from studies that reported information exclusively on abscess formation, as well as data from studies that reported information on "peritonitis" (however defined).

For Key Question 2 we considered the following adverse events: nausea, vomiting, dehydration, electrolyte imbalance (e.g., hypokalemia, hypernatremia), kidney damage, emergency admissions prior to surgery; cancelled, delayed, or rescheduled surgeries, allergic reactions, seizures. Studies reporting any of these prespecified outcomes were included, regardless of causal attribution to OMBP (i.e., regardless of whether the authors of individual reports considered them to be related to OMBP use as opposed to any of the cointerventions); however, we collected information on causal attribution, when available.

[b]Available at www.cdc.gov/hicpac/SSI/002_SSI.html#IB1; accessed February 11, 2013

Timing, Followup Duration, and Setting

We did not select studies on the basis of followup duration and, when possible, outcome data (for all outcomes) were evaluated separately for the preoperative and postoperative periods. We also did not use the setting where studies were conducted as a selection criterion.

Study Designs

For both Key Questions we considered randomized controlled trials (RCTs) comparing OMBP with non-OMBP preparation strategies or alternative active OMBP strategies in patient populations undergoing elective colon or rectal surgery. We required that RCTs enrolled at least 10 subjects per arm; smaller sample sizes were considered unlikely to provide estimates of treatment effects that are adequately precise. We also considered nonrandomized comparative studies (NRCS, prospective or retrospective; observational or experimental) comparing at least two of the interventions of interest in patients undergoing elective colon or rectal surgery. We required that NRCS enrolled at least 100 subjects (per arm); this cutoff was chosen because we expected that adjustments for confounders would be made, and that these would require a minimum sample size. This cutoff is probably lenient.[c]

For Key Question 2, in addition to RCTs and NRCS, we also considered single-group studies (i.e., cohort studies where all patients are managed with OMBP and followed up longitudinally) and then undergo elective colon or rectal surgery. We required that single group studies reported results on at least 200 patients. This cutoff was chosen to ensure that studies would be likely to observe events that have relatively low incidence rates.[d] For Key Question 2b (adverse events in susceptible subgroups) we specifically required that studies reported formal interaction tests or allowed for the calculation of statistics that compare the treatment effect among strata of the modifier of interest.

Data Extraction

A single investigator extracted data from each study; a second reviewer verified quantitative results. Disagreements were resolved by consensus involving a third investigator. Data were extracted into electronic forms stored in the Systematic Review Data Repository[23]; separate forms were generated for each Key Question. Extraction forms were piloted on three to five articles for each Key Question and revisions were made as needed. We extracted information on the following items: patient selection criteria, population characteristics, sample size, study design, analytic details, and outcomes.

We prespecified that we would contact authors for the following reasons: (1) to clarify information reported in the papers that is hard to interpret (e.g., inconsistencies between tables and text); (2) to obtain missing data on key subgroups of interest when not available in the published reports (e.g., location of the surgery—right or left colon, rectum); and (3) to verify suspected overlap between study populations in publications from the same group of

[c]Assuming that at least three potential confounders are to be considered, regression models have to include at least four predictor variables (one per confounder and the treatment indicator). Using the (fairly optimistic) rule of 10, this means that a study should include at least 40 (= 4 × 10) outcome events for statistical analysis. This implies relatively large sample sizes, especially for low incidence rate events: Even if the outcome rate is relatively high, e.g., 10 percent, the sample size needs to be >400 patients, which is much larger than the cutoff employed here.

[d]For example, assuming the true incidence proportion is 0.01 (=1%) the probability of observing at least one event is approximately 87 percent for a study of 200 patients.

investigators. We contacted the corresponding author of each study by email or regular mail to collect additional information. We made a primary contact attempt (once all eligible studies had been identified) and sent two reminder emails (approximately 2 and 4 weeks after the first attempt).

Population Overlap Across Publications

We took particular care to avoid double counting (both in qualitative and quantitative analyses) when published papers reported on potentially (fully or partially) overlapping patient populations. Potential overlap was assessed on the basis of the sampling population of each study, the enrollment period for each publication, the patient selection criteria, and information on overlap provided by the authors in the published papers. When overlap could not be ruled out on the basis of the above criteria, we used a conservative approach of considering as potentially overlapping in any studies conducted by the same investigators. In the presence of suspected overlap we based our analysis on the study reporting the largest number of outcome events (typically, the study reporting on the longest followup for longitudinal studies).

Risk of Bias and Completeness of Reporting of Individual Studies

For assessing the risk of bias, we followed recently updated guidance from the Methods Guide. We used different criteria for assessing the risk of bias (and when appropriate, the completeness of reporting) for each study design. For RCTs, we based our assessment on items derived from the Cochrane risk of bias tool.[24] For NRCSs and single-group studies, we used items from the Newcastle-Ottawa tool[e], with the addition of items relevant to statistical analysis.[25]

We did not merge items into composite quality scores. Instead, we assessed and reported each methodological quality item (as Yes, No, or Unclear/Not Reported) for each eligible study. We rated each study as being of low, intermediate, or high risk of bias on the basis of these items Generally, studies with low risk of bias have the following features: lowest likelihood of confounding due to comparison to a randomized controlled group; a clear description of the population, setting, interventions, and comparison groups; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; clear reporting of dropouts and a dropout rate less than 20 percent; and no apparent bias. Studies with moderate risk of bias are susceptible to some bias but not sufficiently to invalidate results. They do not meet all the criteria for low risk of bias owing to some deficiencies, but none are likely to introduce major bias. Studies with moderate risk of bias may not be randomized or may be missing information, making it difficult to assess limitations and potential problems. Studies with high risk of bias are those with indications of bias that may invalidate the reported findings (e.g., observational studies not adjusting for any confounders, studies using historical controls, or studies with very high dropout rates). These studies have serious errors in design, analysis, or reporting and contain discrepancies in reporting or have large amounts of missing information.

Assessment of risk of bias was outcome specific. For example, a given study that was well designed, conducted and reported with respect to its primary outcome, but did a suboptimal analysis for a secondary outcome was graded of different quality for the two outcomes.

[e]Available at: www.ohri.ca/programs/clinical_epidemiology/oxford.asp; accessed May 30, 2013.

Data Synthesis

Qualitative Synthesis

We summarized the findings of the report according to the order of the Key Questions. Within each Key Question, results were organized for each appropriate subgroup on the basis of the populations assessed, comparisons performed (e.g., OMBP versus no OMBP; or comparisons among alternative OMBP strategies), and outcomes assessed. We used tables and graphs (e.g., weighted scatterplots) to synthesize information across studies.

Single-group studies of OMBP were used to obtain ranges of adverse event rates among patients receiving the interventions of interest. These ranges were used to help contextualize the effects observed in comparative studies, and inform on their applicability.

Quantitative Synthesis

Meta-Analysis

For each comparison of interest, we assessed whether the eligible studies were sufficiently similar ("exchangeable") to be combined in a meta-analysis on the basis of clinical heterogeneity of patient populations and interventions, as well as methodological heterogeneity of study designs and outcomes reported. RCTs and nonrandomized designs (NRCSs and single group studies) were not combined quantitatively because of heterogeneity in the comparisons and outcomes reported, as well as on the basis of concerns regarding risk of bias in nonrandomized studies.

The determination on the appropriateness of meta-analysis was made *before* any data analysis; we did not base the decision to perform a meta-analysis on statistical criteria for heterogeneity. Such criteria are often inadequate (e.g., have low power when the number of studies is small) and do not account for the ability to explore and explain heterogeneity by examining study-level characteristics. Main analyses included all relevant studies (e.g., studies of colon and rectum surgeries and those with mixed populations); subgroup analyses (e.g., separately by anatomic site of surgery, or by year when study enrollment was started) were performed, when possible. In cases where only a subset of the available studies could be quantitatively combined (e.g., when some studies were judged to be so clinically different from others as to be excluded from meta-analysis) we synthesized findings qualitatively by taking into account the magnitude and direction of effects.

Pairwise Meta-Analyses

Direct pairwise meta-analyses were undertaken when there were more than three non-overlapping studies evaluating the same intervention and comparator and reporting the same outcomes. All meta-analyses used random effects models. We fit models in the generalized linear mixed model framework using the binomial family for within study variability and a logit link function (i.e., the odds ratio was the measure of association). Estimation was via Bayesian Markov chain Monte Carlo methods. These methods incorporate uncertainty in the summary estimates of treatment effects more fully than frequentist methods. Heterogeneity was assessed based on the posterior distribution of the between-study heterogeneity parameter. Prior distributions for all model parameters were noninformative and were subjected to extensive sensitivity analyses, including the use of informative priors. Additional sensitivity analyses (including leave-one-out analyses, analyses assuming a fixed effects model, and reanalyses after

excluding a group of studies) where undertaken when deemed important (e.g., in the presence of studies with outlying effect sizes or evidence of temporal changes in effect sizes). We explored between-study heterogeneity using subgroup and meta-regression analyses.

Frequentist meta-analysis methods (which do not require the specification of prior distributions for model parameters) were also used as in sensitivity analyses. In these analyses, for all statistical tests, except those for heterogeneity, statistical significance was defined as a two-sided P-value where $P < 0.05$. Heterogeneity was considered statistically significant when the P-value of Cochran's Q statistic was $P < 0.1$ to account for the low statistical power of the test. Between-study inconsistency was quantified with the I^2 statistic.[26]

Network Meta-Analysis

Network Topology

We used network meta-analysis to jointly analyze evidence on the effectiveness of the following treatment strategies: OMBP, with or without enema, enema alone and no preparation. Studies comparing enema alone and no preparation were not in the scope of this report, and such studies (if any exist) are not included the analyses. This does not induce any bias in estimates of treatment effects obtained from comparisons reported in the included studies (i.e., OMBP versus no preparation; OMBP versus enema).

The topology of the network corresponds to the separate meta-analyses reported in a recent Cochrane Systematic Review.[1] Specifically, in the main analysis we considered OMBP-treated groups as a single network node (i.e., we constructed a 3-node network, comprising OMBP, with or without enema, versus enema alone versus no preparation). Thus, treatment groups receiving OMBP were analyzed together, regardless of the use of enema in conjunction with OMBP. We believe that this analysis represents a compromise between obtaining informative estimates of the relative effects of interventions when few trials are available and the desire for more granular groupings of these interventions. It is also consistent with previous work on the topic.[1] We did not construct or analyze networks that include comparisons between alternative active OMBP interventions, because of substantial concerns that head-to-head studies between active OMBP strategies are not similar to studies included in the above network. Specifically, we observed substantial heterogeneity in the cointerventions, the details of the OMBP strategies, and in the examined outcomes. We also observed that most studies with head-to-head comparisons of OMBP regimens were conducted more than two decades ago (e.g., 60 percent finished enrollment in or before 1990). By contrast, most comparisons of OMBP versus no OMBP (with or without enema) were conducted in more recent years (e.g., 86 percent begun enrollment after 1990). This temporal pattern in the design of OMBP studies parallels evolving trends in surgical practice (e.g., the use of enhanced recovery protocols, use of intravenous antibiotics), and suggests that secular changes have occurred in the characteristics of the enrolled populations and the typical cointerventions/preparation for surgery. This was deemed substantial ground for disputing the similarity between older studies comparing active OMBP strategies, and the more recent ones that compare using versus not using OMBP.

Models and Estimation

Similar to the pairwise analyses, we fit models in the generalized linear mixed model framework using the binomial family for within study variability and a logit link function. Network meta-analyses were performed for all outcomes of interest where several studies (at least 6 studies for at least one of the direct contrasts) existed.[27] Models accounted for between-

study heterogeneity and assumed homogeneity of the random effects variances at the between-study level. This assumption is typical especially when few studies provide information for each edge of the network.

In the main analysis (3-node network) no included study reported a comparison of enema versus no enema. Because the effect size for this comparison is only indirectly estimated, no assessment of consistency between direct and indirect effects is possible. In sensitivity analysis (4-node network), we had a closed loop and therefore the opportunity to test for inconsistency. We did not perform a formal test for inconsistency, but evaluated its presence qualitatively by comparing results from pairwise meta-analyses (direct effects) with results from the network analyses (combined direct and indirect effects). This is because in networks with relatively few and small studies quantitative assessments of inconsistency are very uncertain, and almost noninformative.

Network meta-analysis models were fit using Bayesian Markov Chain Monte Carlo (MCMC) methods because they offer additional modeling flexibility and because they allowed direct probabilistic statements regarding the magnitude and direction of the treatment effect. Prior distributions for all model parameters (including treatment effects and between-study variance components) were noninformative. For example, treatment effect priors did not exclude very large benefits or very large harms, as the variance in the prior for the true log odds ratio was set to 1000. Similarly, priors for variance components were consistent with no heterogeneity as well as very large heterogeneity. The prior for the between-study variance ranged from 0 to 25 on the log-odds ratio scale.

Reporting of Results

We obtained estimates of the treatment effects of interest (e.g., odds ratios for anastomotic leakage comparing OMBP versus no OMBP), as well as the rank probabilities for each treatment strategy (e.g., probability that OMBP is the best treatment). We also estimated probabilities that the difference (in the odds ratio scale) between pairs of treatments was larger than 1.00, 1.10, 1.25, 1.50, 2.00, 3.00, and 5.00 (or smaller than the inverse of these values, to capture extreme effects in the other direction). These cutoffs were chosen after discussion with the TEP.

Subgroup and Meta-Regression Analysis

For pairwise comparisons OMBP versus enema or no preparation we assessed the impact of study-level characteristics on estimates of the effect size, using subgroup and random effects meta-regression analyses. Such analyses were performed for anatomic location (colon versus rectum), year of study publication, and items related to study risk of bias (specifically, randomized sequence generation and allocation concealment).

Small-Study Effects and Publication Bias

We did not use funnel plots or statistical tests of funnel plot asymmetry to assess the presence of small-study effects in pairwise meta-analyses — that is, differences between larger (more precise) and smaller (less precise) studies. Although these methods are sometimes considered as diagnostics for publication bias, theoretical and empirical studies show that they cannot differentiate publication bias from genuine heterogeneity.[28,29] Furthermore, selective outcome reporting, other biases, or chance can also lead to significant results. Because of these reasons, we only provide qualitative dispositions regarding publication bias.

Software

All analyses were performed using Stata IC (version 13.1 Stata Corp., College Station, TX). MCMC methods were implemented in Winbugs (version 1.4.3; MRC Biostatistics Unit, Cambridge, UK), through calls from Stata. Results from Bayesian analyses are reported as medians and 95% central credible intervals (CrI) from the posterior distributions. All frequentist tests were two-sided (except those for heterogeneity) and statistical significance was defined as a P value of less than 0.05. We did not perform any adjustments for multiple comparisons. Graphs were generated in Stata.

Grading the Body of Evidence

We followed the Methods Guide to evaluate the strength of the body of evidence for each Key Question with respect to the following domains: risk of bias, consistency, directness, precision, and reporting bias.

Briefly, we determined *risk of bias* (low, medium, or high) on the basis of the study design and the methodological quality of the studies.

We rated the *consistency* of the data as no inconsistency, inconsistency present, or not applicable (if there is only one study available). We did not use rigid counts of studies as standards of evaluation (e.g., four of five studies agree, therefore the data are consistent); instead, we assessed the direction, magnitude, and statistical significance of all studies and made a determination. We described our logic when studies were not unanimous.

We assessed *directness* of the evidence (direct versus indirect) on the basis of the use of surrogate outcomes or the need for indirect comparisons (e.g., when treatments had not been directly compared and inference was based on observations across studies).

We assessed the *precision* of the evidence as precise or imprecise on the basis of the degree of certainty surrounding each effect estimate. Generally, a precise estimate is one that allows for a clinically useful conclusion. An imprecise estimate is one for which the credible (or confidence) interval is wide enough to include clinically distinct conclusions and that therefore precludes a conclusion.

The potential for *reporting bias* (suspected versus not suspected) was evaluated with respect to publication bias, selective outcome reporting bias, and selective analysis reporting bias. For reporting bias, we provided qualitative dispositions rather than perform formal statistical tests to evaluate differences in the effect sizes between more precise (larger) and less precise (smaller) studies (see above, under Small-Study Effects and Publication Bias). We evaluated the reported results across studies qualitatively, on the basis of completeness of reporting (separately for each outcome of interest), number of enrolled patients, and numbers of observed events. Judgment on the potential for selective outcome reporting bias will be based on reporting patterns for each outcome of interest across studies. We acknowledge that both types of reporting bias are difficult to reliably detect on the basis of data available in published research studies (i.e., without access to study protocols and detailed analysis plans). Although some degree of subjectivity is unavoidable in this assessment, we present explicitly all operational decisions and provide the rationale for our judgment on reporting bias.

Finally, we rated the body of evidence using four strength of evidence levels: high, moderate, low, and insufficient. These ratings describe our level of certainty that the evidence reflects the true effect for the major comparisons of interest.

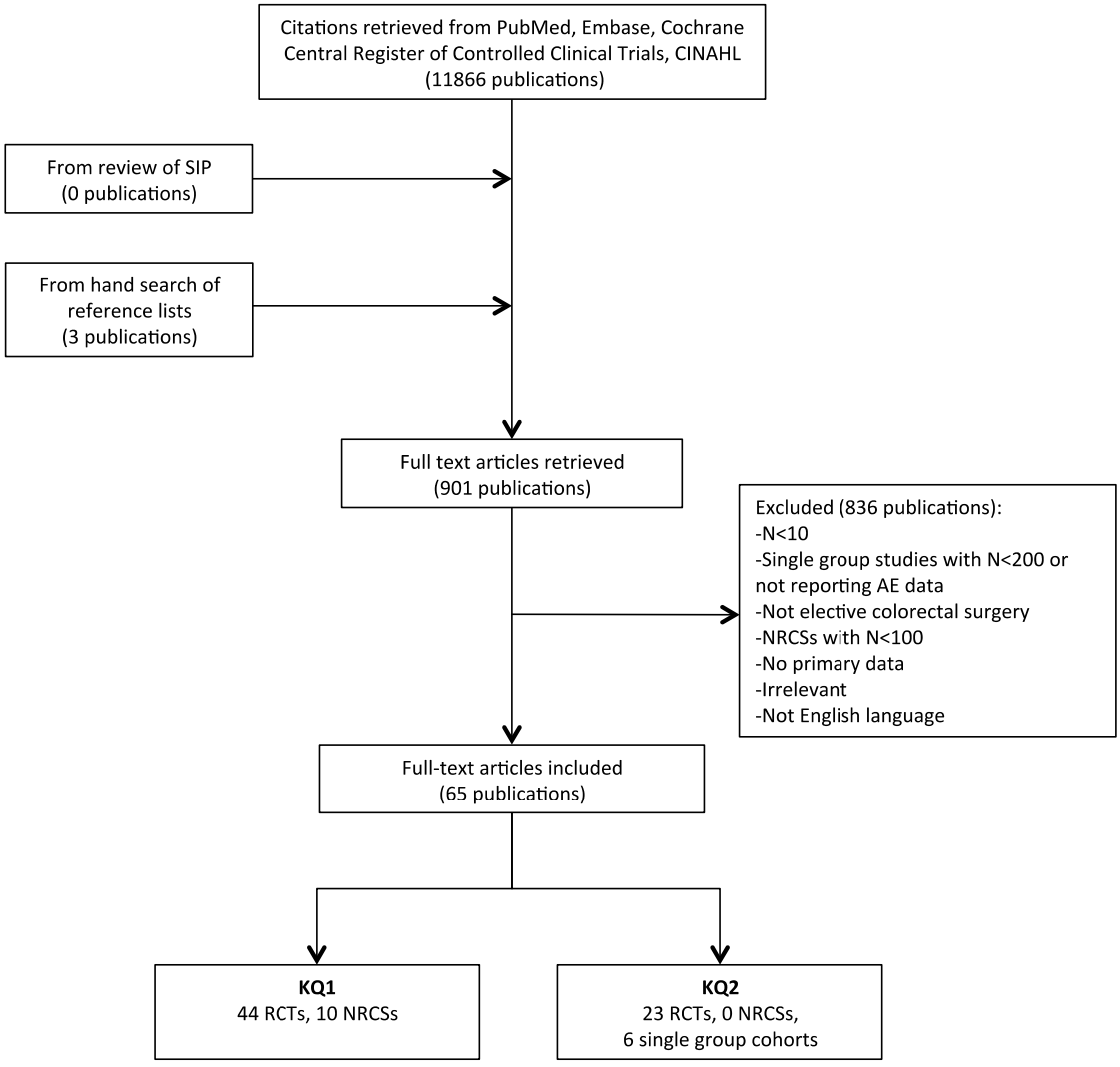
Assessing Applicability

We followed the Methods Guide[30] to evaluate the applicability of included studies to patient populations of interest. We evaluated studies (or subgroups of studies) of elderly adults (operationally defined as patients 65 years of age or older) separately if data are available. Applicability will also be judged separately for various indications of OMBP use (e.g., left-sided versus right-sided colon surgery, rectal surgery), characteristics of the OMBP preparation strategy (e.g., total duration of preparation, inpatient versus outpatient use); patient sex (men versus women), and setting of care.

Results

Our literature search yielded 11,869 citations (11,866 from electronic databases and 3 from hand-searching; no submission information packages were received; Figure 2). Of these, 901 articles were reviewed in full text. After full text review, 60 unique studies (reported in 65 publications[8,11,31-93]) were judged to have met the inclusion criteria for at least one of the Key Questions (44 RCTs; 10 NRCSs; and 6 single-group cohorts). The most common reasons for exclusion of articles were related to study design (e.g., we excluded uncontrolled case series and NRCSs not meeting the sample size cutoffs) and language of publication. See Appendix B for a list of the excluded studies with the reason for exclusion. Data extraction forms and summary tables for all included studies are available online on the Systematic Review Data Repository (http://srdr.ahrq.gov/).

Figure 2. Literature flow diagram



AE = adverse event; CINAHL = Cumulative Index to Nursing and Allied Health Literature; KQ = Key Question; NRCS = non-randomized comparative trial; RCT = randomized controlled trial; SIP = scientific information packet
Note: Some publications reported data from the same study. Detailed reasons for exclusion of studies reviewed in full text but not considered further are presented in Appendix B.

Key Question 1. How do various preoperative OMBP strategies compare between them and versus a control with respect to their effectiveness for preventing surgical or postsurgical complications?

a. For elective right colon surgery?

b. For elective left colon surgery?

c. For elective rectal surgery?

Forty-four RCTs (Table 1) and ten NRCSs met criteria for Key Question 1. Twenty-seven studies compared OMBP versus enema or no preparation (20 RCTs; 7 NRCSs); 25 compared alternative active OMBP strategies (23 RCTs and 2 NRCSs); two studies compared inpatient versus outpatient preparation (1 RCT and 1 NRCS).

One RCT comparing OMBP versus no OMBP has been retracted,[f] and was not included in the main analyses.[78,94] In extensive sensitivity analyses, inclusion of the retracted study did not impact appreciably impact results or conclusions. One RCT was considered to at least partially overlap with another larger trial and was excluded from main analyses. Two RCTs that enrolled exclusively children are discussed separately. Among studies enrolling adults, one compared the same OMBP regimen in the inpatient versus outpatient setting, and is also described separately.

[f]The retraction notice stated: "large portions of text … have been duplicated from another article previously published in Annals of Surgery". In fact, the text (but not the numerical data) in the two publications is identical (despite being conducted by different research teams based in different countries), raising concerns about the truthfulness of reporting in the second study.

Table 1. Bowel preparation strategies in included RCTs

Author, Year [PMID]	OMBP (per arm)	Enema Used (per arm)	Oral Antibiotics Used (per arm)	Parenteral Antibiotics Used (per arm)
Comparisons of OMBP vs. Enema or no Preparation				
Hughes, 1972[55] [4621021]	bisacodyl/no OMBP	yes/no	unclear/unclear	yes/yes
Burke, 1994[39] [8044619]	Na picosulphate/no OMBP	no/no	no/no	yes/yes
Santos, 1994[76] [7827905]	mineral oil, agar, phenolphthalein + mannitol/ no OMBP	yes/no	no/no	yes/yes
Miettinen, 2000[67] [10826429]	PEG/no OMBP	no/no	no/no	yes/yes
Zmora, 2003[92,93] [12616120]	PEG/no OMBP	selective/selective	yes/yes	yes/yes
Bucher, 2005[38] [15786427]	PEG/no OMBP	no/selective	no/no	yes/yes
Fa-Si-Oen, 2005[49] [15981065]	PEG/no OMBP	no/no	no/no	yes/yes
Platell, 2006[73] [16491463]	PEG/no OMBP	no/yes	no/no	yes/yes
Contant, 2007[44,85,86] [18156032]	PEG or NaP/no OMBP	no/no	no/no	yes/yes
Ali, 2007[31] [not indexed]	WGI with saline/non OMBP	no/no	unclear/unclear	unclear/unclear
Jung, 2007[57,58] [17514668]	PEG or NaP/no OMBP	no/no	yes/yes	yes/yes
Pena-Soria, 2008[8,72] [18820977]	PEG/no OMBP	yes/no	no/no	yes/yes
Bretagnol, 2010[36] [21037443]*	senna/no OMBP	yes/no	no/no	yes/yes
Scabini, 2010[78] [20433721]	PEG/no OMBP	selective/selective	no/no	yes/yes
Watanabe, 2010[87] [20799286]	MgCitrate/no OMBP	yes/no	no/no	yes/yes
Bertani, 2011[35] [21689356]	PEG/no OMBP	yes/yes	no/no	yes/yes
Khan, 2011[59] [not indexed]	Na picosulphate/no OMBP	no/no	no/no	yes/yes
Sasaki, 2012[77] [22976604]	PEG + Na picosulfate/no OMBP	no/no	no/no	yes/yes
Tahirkheli, 2013[81] [not indexed]	WGI with saline/no OMBP	no/no	yes/no	yes/yes
Comparisons of Alternative OMBP Strategies in Adults				
Matheson, 1978[66] [359083]	MgSulphate/nutritional	yes/yes	yes/yes	no/no
Chung, 1979[43] [365010]	MgCitrate/WGI with Ringer's	yes/no	no/no	yes/yes
Christensen, 1981[42] [7318622]	WGI with NaCl, $NaHCO_3$, KCl/sodium salt solution	no/yes	no/no	yes/yes
Morris, 1983[68] [6190888]	senna/mannitol	no/no	no/no	yes/yes

Table 1. Bowel preparation strategies in included RCTs (continued)

Author, Year [PMID]	OMBP (per arm)	Enema Used (per arm)	Oral Antibiotics Used (per arm)	Parenteral Antibiotics Used (per arm)
Comparisons of Alternative OMBP Strategies in Adults (continued)				
Beck, 1985[34] [4017808]	senna + MgCitrate/PEG+bisacodyl	yes/no	no/no	yes/yes
Fleites, 1985[50] [3901374]	PEG/bisacodyl + MgCitrate	unclear/unclear	yes/yes	yes/yes
Panton, 1985[71] [3887955]	castor oil or MgSulfate/WGI with Ringer's	unclear/yes	no/no	yes/yes
Beck, 1986[11] [3095080]	PEG/mannitol	no/no	no/no	yes/yes
Dueholm, 1987[46] [3552504]	PEG/WGI with NaCl solution	no/no	no/no	yes/yes
Wolff, 1988[88] [3132910]	WGI with PEG/NaP	no/yes	yes/yes	yes/yes [for a subset of patients]
Soballe, 1989[80] [2499830]	PEG/bisacodyl + MgCitrate	no/yes	yes/yes	no/no
Beck, 1991[33] [2021332]	PEG/senna + MgCitrate	no/yes	no/no	yes/yes
Wolters, 1994[89] [8205446]	PEG/WGI with Ringer's/bisacodyl + NaP	no/no/no	no/no/no	no/no/no
Grundel, 1997[52] [9369111]	PEG/PEG+bisacodyl+NaP	no/no	no/no	yes/yes
Oliveira, 1997[70] [9152189]	PEG/NaP	no/no	yes/yes	no/no
Makino, 1998[65] [9496494]	senna + MgCitrate/PEG + senna	yes/no	yes/yes	no/no
Valverde, 1999[83] [10323423]	PEG/senna	yes/yes	no/no	yes/yes
Yoshioka, 2000[90] [10720834]	Na picosulphate/NaP	no/no	no/no	no/no
Koussidis, 2001[62] [11841079]	WGI with Ringer's/gastrografin	no/no	unclear/unclear	yes/yes
Reddy, 2007[75] [17443852]	Na picosulphate + MgCitrate/Na picosulphate + MgCitrate/Na picosulphate + MgCitrate/ nutritional	no/no/no/no	no/yes/yes/yes	no/no/no/no
Horvat, 2010[54] [20517667]	PEG + senna/nutritional/nutritional	no/no/no	unclear/unclear/ unclear	unclear/unclear/ unclear

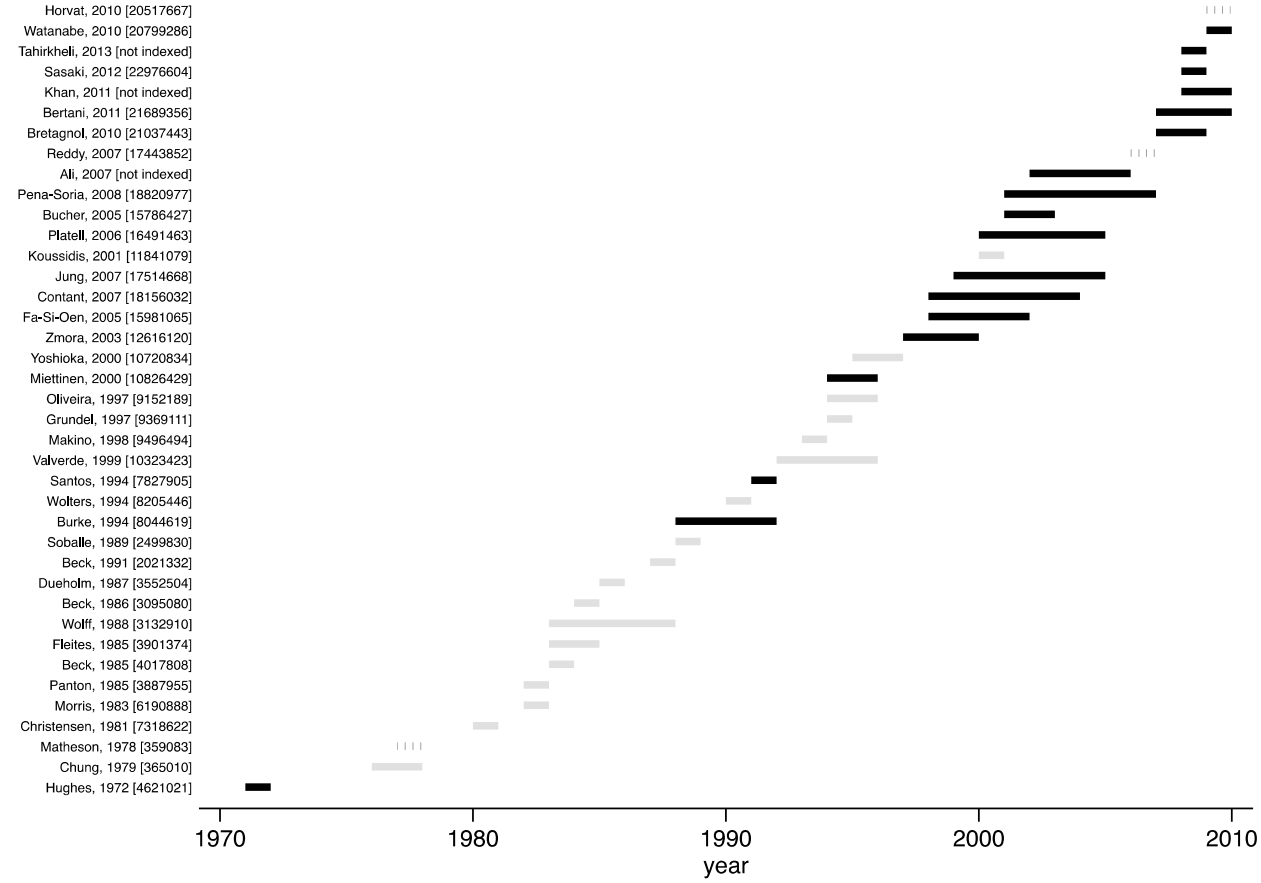
Table 1. Bowel preparation strategies in included RCTs (continued)

Author, Year [PMID]	OMBP (per arm)	Enema Used (per arm)	Oral Antibiotics Used (per arm)	Parenteral Antibiotics Used (per arm)
Comparison of Inpatient vs. Outpatient OMBP				
Frazee, 1992[51] [1740065]	PEG/PEG	yes/yes	yes/yes	yes/yes
Comparisons of Alternative OMBP Strategies in Children				
Chattopadhyay, 2004[41] [14752676]	PEG/WGI with NaCl + KCl	no/no	no/no	yes/yes
Sinha, 2007[79] [17394002]	WGI with PEG/WGI with NaCl solution/WGI with Ringer's	no/no/no	no/no/no	yes/yes/yes

OMBP = oral mechanical bowel preparation; PMID = PubMed identification number; PEG = polyethylene glycol; WGI = whole gut irrigation
*Retracted study.
Note: A possible duplicate study is not included in the table.[37]

We classified the remaining 39 RCTs into two mutually exclusive groups: trials comparing OMBP versus no OMBP (with or without enema) – active versus inactive comparison; and trials comparing alternative active OMBP strategies – active versus active comparison. Studies belonging to the latter group were conducted in earlier years (median year of enrollment start = 1986), followed by studies investigating the omission of OMBP (median year of enrollment start = 2001). Figure 3 depicts this temporal pattern.

Figure 3. Enrollment periods for RCTs comparing OMBP versus no OMBP and alternative OMBP strategies



Note: The information in the figure includes only RCTs conducted in adult or mixed populations (i.e. studies exclusively enrolling children are not shown). Studies of inpatient vs. outpatient OMBP are also not shown. Horizontal lines denote the trial enrollment period (from enrollment start to end). Black lines denote trials comparing OMBP versus no OMBP; solid gray lines denote trials comparing alternative active OMBP preparations, and dashed gray lines denote nutritional preparation methods (prebiotics or symbiotics, with or without OMBP. Studies are plotted by year of enrollment start and then by year of publication. For studies not reporting the enrollment period we used the year of publication as the last year of enrollment and assumed a trial duration of one year.

The two groups of studies also differed with respect to the type, duration, and intensity of preparation, as well as the administered cointerventions (Table 2). For example, OMBP by whole gut irrigation with electrolyte solutions other than polyethylene glycol (PEG) was a comparator in seven OMBP-treated arms in older studies, but in only two OMBP-treated arms in more recent studies (both of which were conducted in Pakistan). (Whole gut irrigation is often done through a nasogastric tube, and is more invasive than oral administration; PEG is one of the most

commonly used solutions nowadays.) Most importantly, perioperative intravenous or intramuscular antibiotics were used in almost all studies comparing OMBP versus no OMBP (one study provided unclear information) but only in 26 of the 46 OMBP-treated arms in trials comparing alternative active OMBP preparations. The total duration of patient preparation for surgery also declined over time (Figure 4), indicating that older studies may have used more aggressive preoperative preparation strategies. Indeed, dietary modification of several days duration, repeated enemas, and multiday OMBP regimens were more often or even exclusively used in the older studies (Group 2).

Further, studies conducted in recent years tended to be better designed, with more studies reporting the conduct of a prospective power calculation (8 of 18 vs. 4 of 20). Reporting of randomization methods and allocation concealment was also generally better in recent studies.

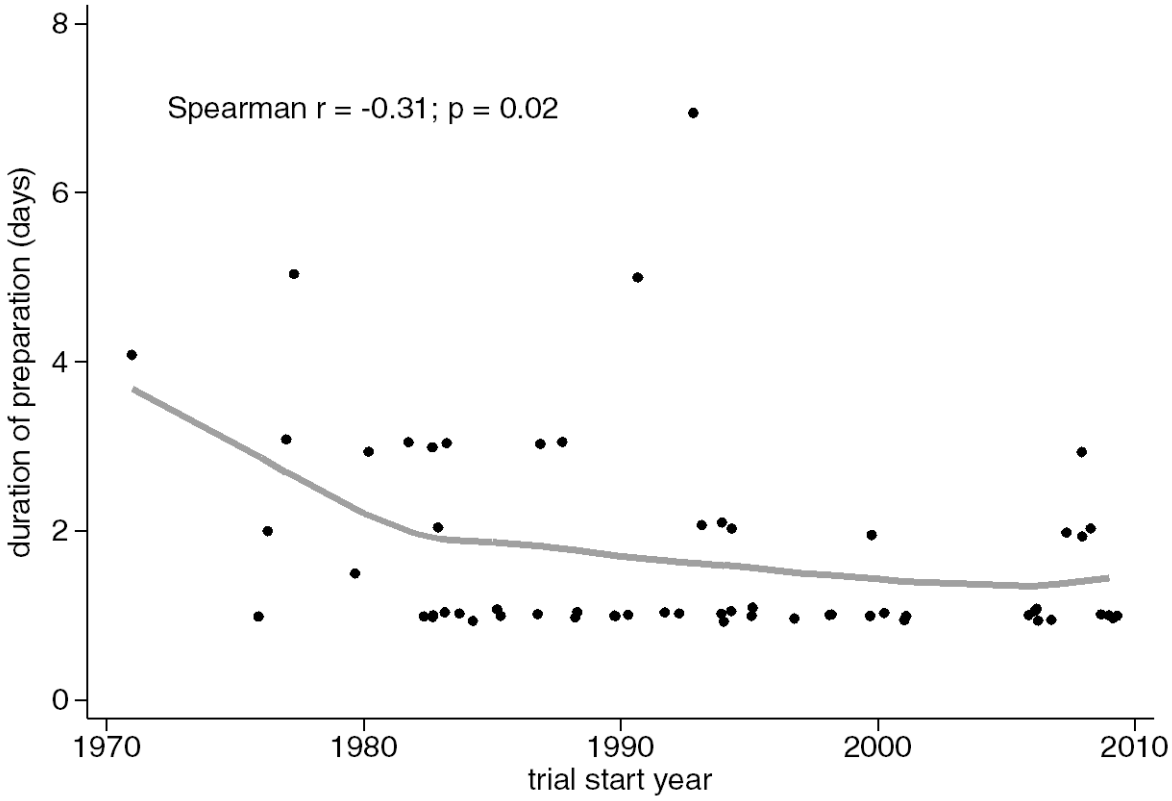
Because of the aforementioned differences between studies of OMBP versus no OMBP and studies of active versus active OMBP comparisons with respect to design, interventions, and cointerventions, we review the findings separately by group.

Table 2. Study design aspects and OMBP methods used in included RCTs

Study Characteristics		Trials Comparing OMBP vs. no OMBP(18 Trials With 18 OMBP-Treated Arms)	Trials Comparing Alternative Active OMBP Strategies (21 Trials With 46 OMBP-Treated Arms)
Study design and surgical technique	Median year starting enrollment	2001	1986
	Median number of included patients	178	92
	Reported performing a power calculation	8 (44%)	5 (24%)
	Study conducted in the U.S.	0 (0%)	6 (29%)
	At least some patients treated with laparoscopic surgery	5 (33%)	2 (10%)
OMBP strategy (in OMBP-treated groups)	PEG	7 (39%)	10 (22%)
	Laxatives or cathartics	5 (28%)	16 (35%)
	PEG + laxatives/cathartics	1 (6%)	3 (7%)
	Hyperosmotic sodium solutions	0 (0%)	3 (7%)
	Whole gut irrigation with electrolyte solution (non-PEG)	2 (11%)	7 (15%)
	Dietary modifications (symbiotics/prebiotics)	0 (0%)	4 (9%)
	Mixed/other	3 (17%)	3 (7%)
Planned administration through NG tube (in OMBP-treated groups)		2 (0%)	8 (17%)
Cointerventions (in OMBP-treated groups)	IV antibiotics	17 (94%)	26 (57%)
	Oral antibiotics	3 (17%)	15 (33%)
	Enema	6 (33%)	12 (26%)

IV = intravenous; NG = nasogastric; OMBP = oral mechanical bowel preparation; PEG = polyethylene glycol
Note: Limited to studies of adult patients. Percentages have been rounded to the nearest integer.

Figure 4. Change in the duration of surgical preparation over time



Note: Limited to RCTs conducted in adult patients. Each dot represents an OMBP-treated arm. Markers have been jittered to make all OMBP-treated groups visible. A smoothed gray line is plotted to help visualize the association.

Ability To Evaluate the Effects of OMBP Separately by Anatomic Location

For Key Question 1 we planned to perform a detailed subgroup analysis of the effects of OMBP according to the anatomic location of the surgical procedures performed. However, of the 43 included RCTs, two enrolled exclusively patients undergoing colonic surgery and another enrolled exclusively patients undergoing rectal surgery. The remaining studies (n=40) enrolled mixed populations of patients undergoing both colon and rectal surgery, or did not provide details regarding anatomic location. Using information provided by the corresponding authors of studies included in this report (directly to us or to the authors of a recent Cochrane report), we were able to identify the anatomic location (colon versus rectum) only for the outcome of anastomotic leakage, and only for the comparison of OMBP versus enema or no preparation. These results are presented below.

Comparisons of OMBP Versus No OMBP

Twenty RCTs and seven NRCSs compared OMBP versus no use of mechanical preparation. One RCT was reported in two papers, but it was not possible to deduce whether the two

publications were in disjoint or overlapping sets of patients.[g] To avoid double-counting, we did not use information from the publication reporting the smallest number of participants (50 patients).[37] Even if said publications describe disjoint groups of patients, it is unlikely that excluding the smaller group changes our results or conclusions (only four clinical events were reported in that group—3 wound abscesses and 1 anastomotic leakage). We excluded from the main analysis a RCT described in a paper that was retracted because its text duplicated large portions from a previously published paper reporting the results of a different study, leaving a total of 18 RCTs and seven NRCSs.

All but two studies enrolled adult patients (or did not provide relevant information). Two RCTs explicitly reported that the study population consisted of both adults and children, but did not report results stratified by age group.[76] Because children are probably the minority of the study sample, and for consistency with previous work, we included these studies together with studies enrolling exclusively adults.[1] In sensitivity analyses, we assessed the robustness of our results to their removal from the dataset.

Common indications for surgery were colorectal cancer and diverticular disease; seven studies explicitly reported excluding patients with inflammatory bowel disease and three studies enrolled exclusively patients with colorectal cancer. Details on the surgical approach (e.g., operation types, anastomosis methods, open versus surgical surgery) were generally incompletely reported.

Direct Comparisons of OMBP Versus No OMBP in RCTs

In our main analyses, 18 RCTs reported comparisons of OMBP strategies versus strategies omitting OMBP. In six studies all participants in OMBP-treated groups received enemas. In one study enemas were administered only to patients with rectal cancer, and 11 studies did not administer enemas in the OMBP-treated groups. In their comparator groups, two studies used enemas for all participants, two studies administered enemas to patients undergoing rectal surgery, and 14 studies did not use any enema. In our main analyses, following previous work, we examined separately the comparisons of OMBP (with or without enema) versus enema, and OMBP versus no enema.

Studies used a variety of OMBP regimens: seven studies used PEG, five studies used other laxatives or cathartics, and six studies used other methods. Almost all studies reported using intravenous antibiotics in the perioperative period (1 study provided unclear information) and three studies reported also using oral antibiotics.

The majority of RCTs were considered to be at moderate risk of bias. Overall, based on the number of items considered indicative of low risk, eight studies were considered to be at high risk of bias, nine to be at moderate risk of bias, and one to be at low risk of bias. Additional details on risk of bias of individual studies are provided in the relevant section, below.

Table 3 presents a summary of the results of our main analysis for outcomes where meta-analysis was possible. The following sections present detailed results for each outcome of interest, followed by the results of sensitivity analyses. Throughout this section, odds ratio (OR) values lower than 1 indicate benefit (i.e., decreased incidence of complications) in OMBP treated patients, as compared to controls. Analyses are stratified by use of enema in the control group

[g]We contacted the corresponding author of these two publications to obtain additional information, however we have received no response as of September 24, 2013.

(i.e., OMBP versus enema and OMBP versus no preparation); combined analyses of all studies (OMBP versus no OMBP) are also presented in forest plots.

Table 3. Summary of meta-analysis results for the comparison of OMBP versus enema or no preparation

Outcome	Comparison	N Studies (N Events/N Patients, per Group)	OR (95% CrI)	Between-Study Variance (95% CrI) [log-odds ratio scale]
All-cause mortality	OMBP ± enema vs. enema/no prep	14 (45/2,550 vs. 44/2,544)	1.17 (0.67 to 2.67)	0.12 (0.00 to 1.99)
	OMBP ± enema vs. no prep	10 (38/2,024 vs. 40/2,014)	1.09 (0.57 to 2.99)	0.17 (0.00 to 2.61)
	OMBP ± enema vs. enema	4 (7/526 vs. 4/530)	1.99 (0.27 to 18.45)	0.82 (0.00 to 3.76)
Anastomotic leakage	OMBP ± enema vs. enema/no prep	16 (126/2,702 vs. 124/2,680)	1.08 (0.79 to 1.63)	0.08 (0.00 to 0.72)
	OMBP ± enema vs. no prep	12 (102/2,176 vs. 103/2,150)	1.06 (0.73 to 1.73)	0.09 (0.00 to 0.95)
	OMBP ± enema vs. enema	4 (24/526 vs. 21/530)	1.24 (0.38 to 4.72)	0.61 (0.00 to 3.59)
Wound Infection	OMBP ± enema vs. enema/no prep	16 (266/2,612 vs. 239/2,603)	1.19 (0.93 to 1.63)	0.04 (0.00 to 0.41)
	OMBP ± enema vs. no prep	12 (218/2,086 vs. 190/2,073)	1.27 (0.95 to 1.88)	0.05 (0.00 to 0.50)
	OMBP ± enema vs. enema	4 (48/526 vs. 49/530)	1.04 (0.37 to 3.34)	0.52 (0.00 to 3.46)
Peritonitis/ intra-abdominal abscess	OMBP ± enema vs. enema/no prep	14 (51/2,381 vs. 70/2,362)	0.84 (0.50 to 1.66)	0.25 (0.00 to 1.77)
	OMBP ± enema vs. no prep	10 (45/1,855 vs. 64/1,832)	0.84 (0.45 to 2.00)	0.38 (0.00 to 2.74)
	OMBP ± enema vs. enema	4 (6/526 vs. 6/530)	0.99 (0.21 to 4.68)	0.42 (0.00 to 3.51)
Reoperation	OMBP ± enema vs. enema/no prep	8 (124/1,967 vs. 119/1,945)	1.14 (0.57 to 2.65)	0.38 (0.00 to 3.23)
	OMBP ± enema vs. no prep	6 (117/1,742 vs. 111/1,723)	1.15 (0.73 to 2.50)	0.09 (0.00 to 1.82)
	OMBP ± enema vs. enema	2 (7/225 vs. 8/222)	0.50 (0.03 to 6.12)	2.49 (0.27 to 3.93)
SSI	OMBP ± enema vs. enema/no prep	7 (206/1,279 vs. 197/1,230)	1.19 (0.56 to 2.63)	0.64 (0.11 to 2.91)
	OMBP ± enema vs. no prep	5 (173/1,087 vs. 171/1,040)	1.10 (0.41 to 3.05)	0.76 (0.10 to 3.39)
	OMBP ± enema vs. enema	2 (33/192 vs. 26/190)	1.50 (0.24 to 10.42)	1.20 (0.02 to 3.79)

CrI = credible interval; no prep = no OMBP and no enema; OMBP = oral mechanical bowel preparation (with or without enema); OR = odds ratio; SSI = surgical site infection.
Note: OR values lower than 1 indicate that events are less common among OMBP-treated groups (i.e., that OMBP is beneficial).

All-Cause Mortality

OMBP Versus No Preparation

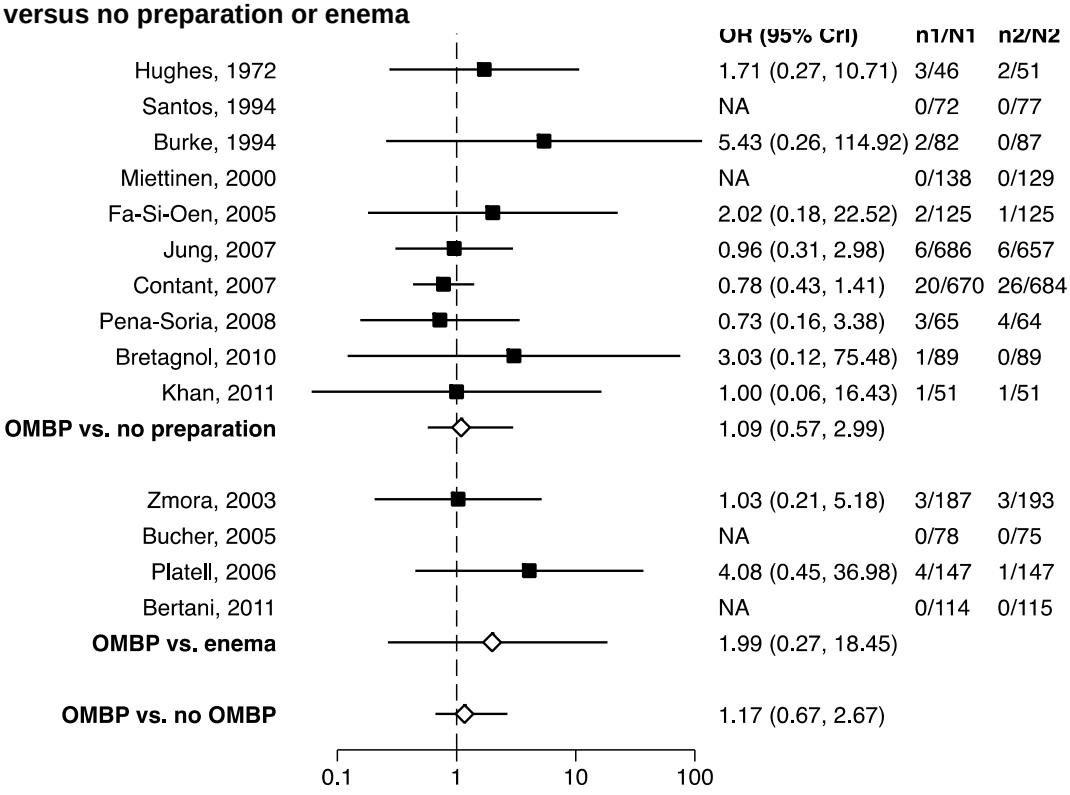
Ten RCTs comparing OMBP versus no preparation reported information on all cause mortality; eight of these reported the occurrence of at least one death. Study sizes ranged from 97 to 1354. Death was relatively rare (78 events in total across all nine studies). The summary OR for all-cause mortality for OMBP versus no preparation was 1.09 (95% CrI 0.57 to 2.99). However, the estimate was imprecise, reflecting the relatively small number of patients

contributing information to the meta-analysis and the small number of observed events. There was little evidence of between-study heterogeneity but there was substantial uncertainty for this parameter: the posterior distribution of the between-study variance of the log-OR had a median of 0.17 (95 CrI, 0 to 2.61). Figure 5 presents the meta-analysis results, along with study-specific event rates.

OMBP Versus Enema

Four RCTs comparing OMBP versus enema reported information on all-cause mortality (2 studies employed a strategy of selective enema use in patients undergoing elective colorectal surgery). Two of the four studies reported the occurrence of at least one outcome event. Studies were small (minimum = 153; maximum = 380) and reported a small number of outcome events (11 events total). The summary OR for all-cause mortality for OMBP versus enema was 1.99 (95% CrI 0.27 to 18.45). However, the estimate was very imprecise, reflecting the relatively small number of patients contributing information to the meta-analysis and the small number of observed events. There was some evidence of between-study heterogeneity but there was substantial uncertainty for this parameter: the posterior distribution of the between-study variance of the log-OR had a median of 0.82 (95 CrI, 0 to 3.76). Figure 5 presents the meta-analysis results, along with study-specific event rates.

Figure 5. All-cause mortality meta-analysis results for studies comparing OMBP (with or without enema) versus no preparation or enema



CI = confidence interval; CrI = credible interval; NA = not applicable; OMBP = oral mechanical bowel preparation; OR = odds ratio

Note: The solid squares (and horizontal lines) indicate the point estimate of the OR (and the corresponding 95% CI) for individual studies; the diamonds (and horizontal lines) indicate the summary estimate of the OR (and corresponding 95% central CrI). The numbers of events and the sample size of each treatment group are shown to the right of the plot. The dashed line indicates an OR of 1.

Cause-Specific Mortality

OMBP Versus No Preparation

Only two studies comparing OMBP versus no preparation reported information on mortality, stratified by cause of death.[8,55] The causes investigated included death due to chest infections, peritonitis, pulmonary embolism, and anastomotic leakage. Each study reported information on different causes of death. None of the comparisons were statistically significant and study-specific estimates of effect were very imprecise. Thus, no clinically meaningful conclusions could be reached.

OMBP Versus Enema

Only two studies comparing OMBP versus enema reported information on mortality, stratified by cause of death.[73,93] The causes investigated included death due to infectious causes, anastomotic leakage, and cardiovascular causes (further stratified into deaths due to congestive heart failure, cardiac arrest, and acute myocardial infarction). Each study reported information on different causes of death. None of the comparisons were statistically significant and study-specific estimates of effect were very imprecise. Therefore, no clinically meaningful conclusions could be reached.

Anastomotic Leakage

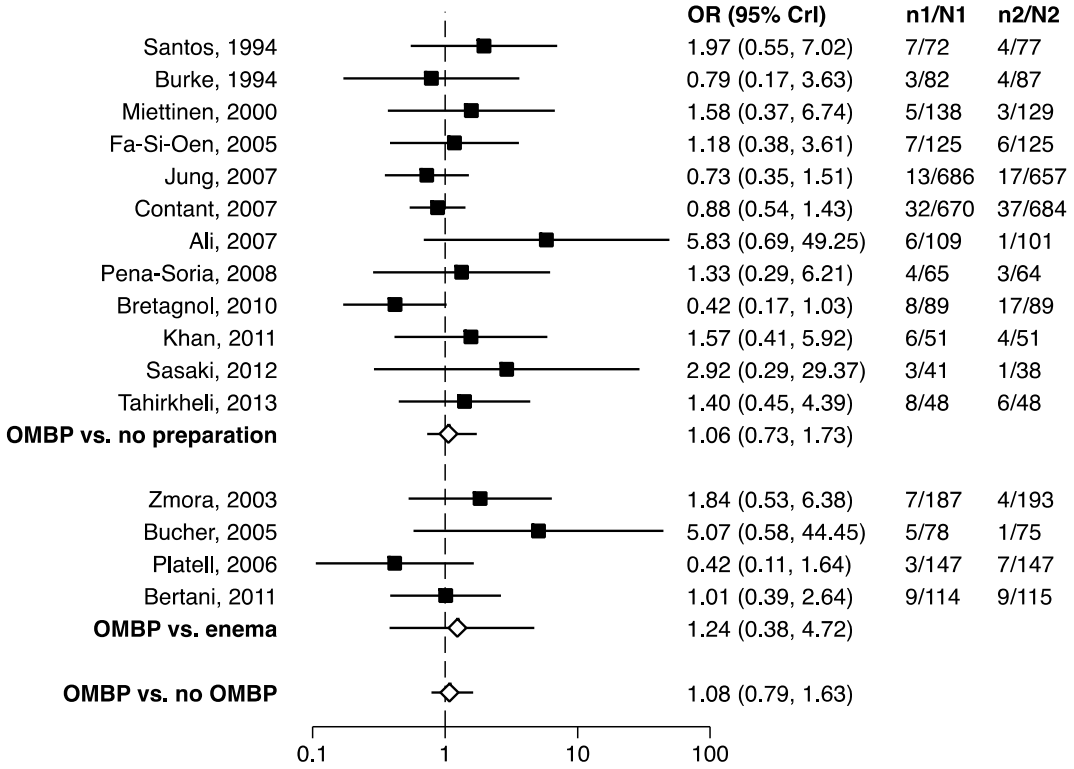
OMBP Versus No Preparation

Twelve RCTs comparing OMBP versus no preparation reported information on anastomotic leakage; all studies reported the occurrence of at least one outcome event. Study sample size ranged from 79 to 1354. The total number of outcome events across all 12 studies was 205, i.e., events were relatively rare. The summary OR for anastomotic leakage in OMBP-treated patients versus controls was 1.06 (95% CrI 0.73 to 1.73). However, the estimate was somewhat imprecise, reflecting the relatively small number of patients contributing information to the meta-analysis and the small number of observed events. There was little evidence of between-study heterogeneity but there was uncertainty for this parameter: the posterior distribution of the between-study variance of the log-OR had a median of 0.09 (95 CrI, 0 to 0.95). Figure 6 presents the meta-analysis results, along with study-specific event rates.

OMBP Versus Enema

Four RCTs comparing OMBP versus enema reported information on anastomotic leakage (2 studies employed a strategy of selective enema use in patients undergoing elective colorectal surgery); all studies reported the occurrence of at least one outcome event. Studies were small (minimum = 153; maximum = 380) and reported a small number of outcome events (45 events total). The summary OR for all-cause mortality in OMBP-treated patients versus controls was 1.24 (95% CrI 0.38 to 4.72). This estimate was imprecise, reflecting the relatively small number of patients contributing information to the meta-analysis and the small number of observed events. There was some evidence of between-study heterogeneity but there was substantial uncertainty for this parameter: the posterior distribution of the between-study variance of the log-OR had a median of 0.61 (95 CrI, 0 to 3.59). Figure 6 presents the meta-analysis results, along with study-specific event rates.

Figure 6. Anastomotic leakage meta-analysis results for studies comparing OMBP (with or without enema) versus no preparation or enema



CI = confidence interval; CrI = credible interval; NA = not available (could not be estimated); OMBP = oral mechanical bowel preparation; OR = odds ratio

Note: The solid squares (and horizontal lines) indicate the point estimate of the OR (and the corresponding 95% CI) for individual studies; the diamonds (and horizontal lines) indicate the summary estimate of the OR (and the corresponding 95% central CrI). The numbers of events and the sample size of each treatment group are shown to the right of the plot. The dashed line indicates an OR of 1.

Wound Infection

OMBP Versus No Preparation

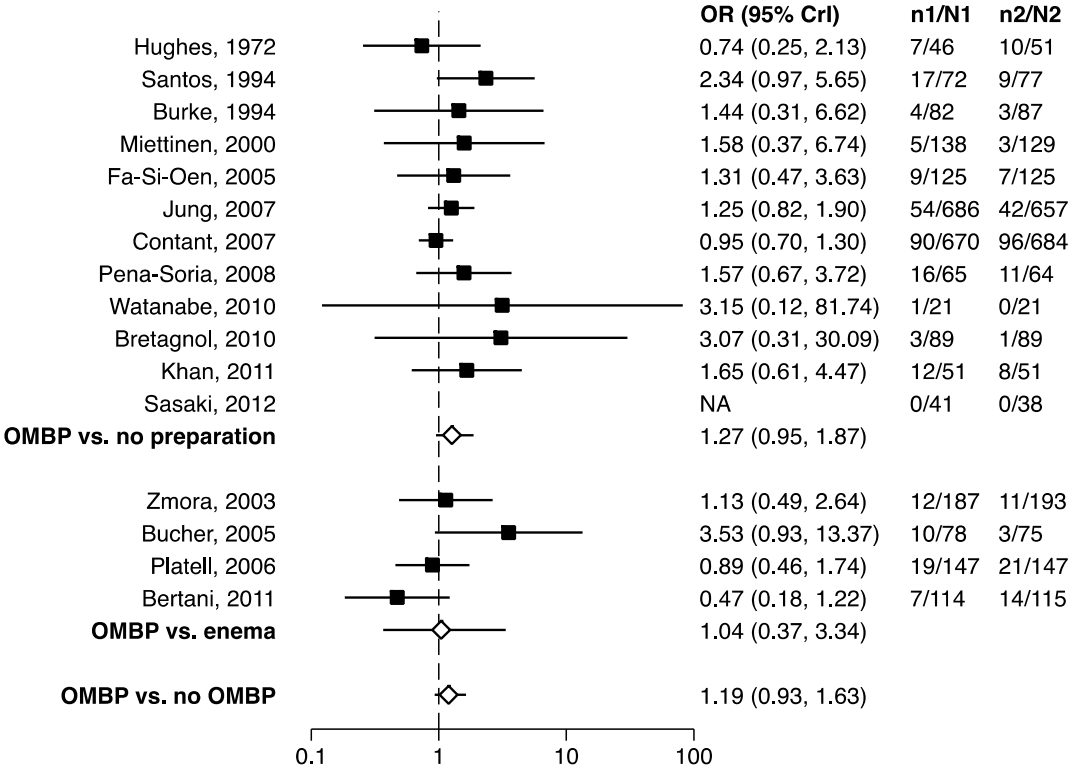
Twelve RCTs comparing OMBP versus no preparation reported information on wound infection; eleven studies reported the occurrence of at least one outcome event in either arm. Studies had varying sample sizes (minimum = 42; maximum = 1354) and reported a total of 388 outcome events. The summary OR for wound infection was 1.27 (95% CrI 0.95 to 1.88). There was little evidence of between-study heterogeneity but there was uncertainty for this parameter: the posterior distribution of the between-study variance of the log-OR had a median of 0.05 (95 CrI, 0 to 0.5). Figure 7 presents the meta-analysis results, along with study-specific event rates.

OMBP Versus Enema

Four RCTs comparing OMBP versus enema reported information on wound infection (2 studies employed a strategy of selective enema use in patients undergoing elective colorectal surgery); all studies reported the occurrence of at least one outcome event. Studies were small (minimum sample size= 153; maximum = 380) and reported a total of 97 outcome events. The summary OR for wound infection was 1.04 (95% CrI 0.37 to 3.34). There was some evidence of

between-study heterogeneity but there was substantial uncertainty for this parameter: the posterior distribution of the between-study variance of the log-OR had a median of 0.52 (95 CrI, 0 to 3.46). Figure 7 presents the meta-analysis results, along with study-specific event rates.

Figure 7. Wound infection meta-analysis results for studies comparing OMBP (with or without enema) versus no preparation or enema



CI = confidence interval; CrI = credible interval; NA = not available (could not be estimated); OMBP = oral mechanical bowel preparation; OR = odds ratio

Note: The solid squares (and horizontal lines) indicate the point estimate of the OR (and the corresponding 95% CI) for individual studies; the diamonds (and horizontal lines) indicate the summary estimate of the OR (and the corresponding 95% central CrI). The numbers of events and the sample size of each treatment group are shown to the right of the plot. The dashed line indicates an OR of 1.

Peritonitis or Intra-Abdominal Abscess

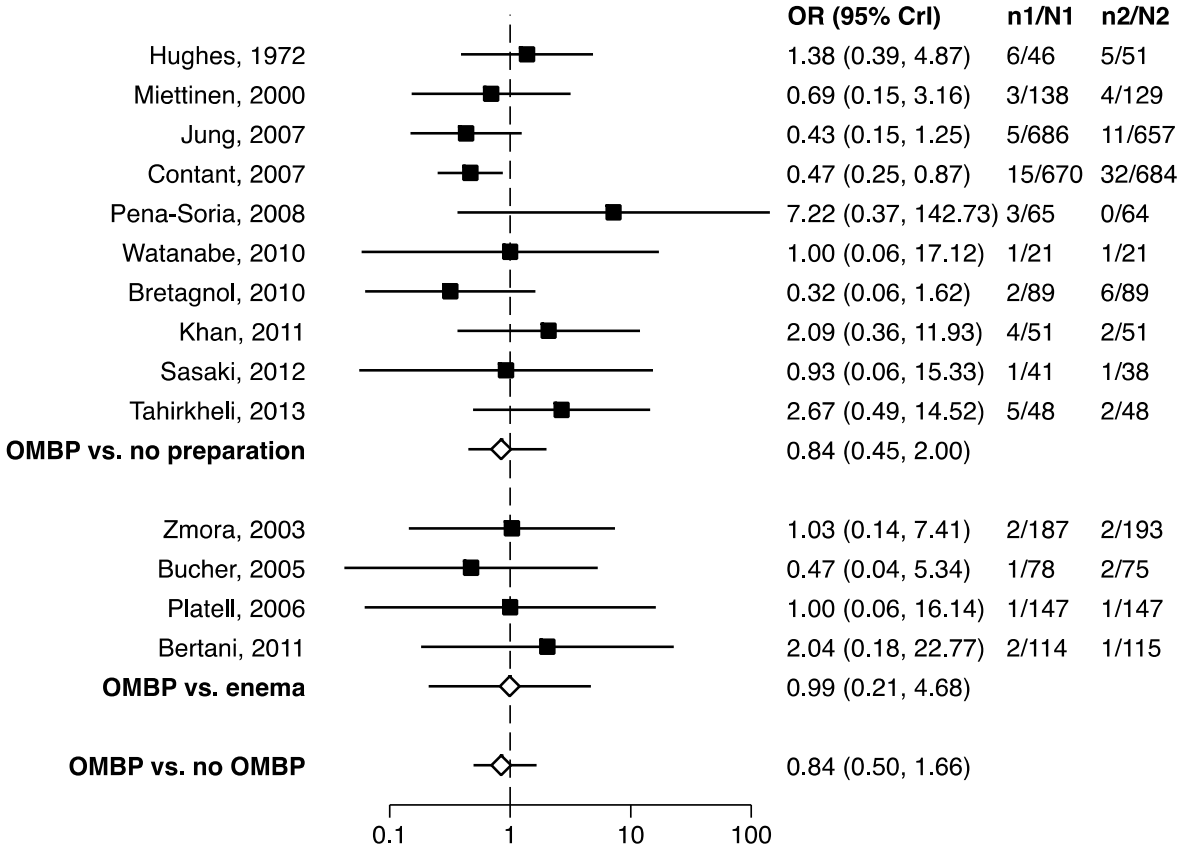
OMBP Versus No Preparation

Ten RCTs comparing OMBP versus no preparation reported information on peritonitis or intra-abdominal abscess development; all studies reported the occurrence of at least one outcome event. Studies had varying sample sizes (minimum = 42; maximum = 1354) and reported a small number of outcome events (109 events total). The summary OR for peritonitis or intra-abdominal abscess development was 0.84 (95% CrI 0.45 to 2.00). However, the estimate was somewhat imprecise, reflecting the relatively small number of patients contributing information to the meta-analysis and the small number of observed events. There was some evidence of between-study heterogeneity but there was substantial uncertainty for this parameter: the posterior distribution of the between-study variance of the log-OR had a median of 0.38 (95 CrI, 0 to 2.74). Figure 8 presents the meta-analysis results, along with study-specific event rates.

OMBP Versus Enema

Four RCTs comparing OMBP versus enema reported information on peritonitis or intra-abdominal abscess development (2 studies employed a strategy of selective enema use in patients undergoing elective colorectal surgery); seven studies reported the occurrence of at least one outcome event. Studies were small (minimum = 153; maximum = 380) and reported a small number of outcome events (12 events total). The summary OR for peritonitis or intra-abdominal abscess development, comparing OMBP-treated patients versus controls was 0.99 (95% CrI 0.21 to 4.68). There was some evidence of between-study heterogeneity but there was substantial uncertainty for this parameter: the posterior distribution of the between-study variance of the log-OR had a median of 0.42 (95 CrI, 0 to 3.51). Figure 8 presents the meta-analysis results, along with study-specific event rates.

Figure 8. Peritonitis/intra-abdominal abscess meta-analysis results for studies comparing OMBP (with or without enema) versus no preparation or enema



CI = confidence interval; CrI = credible interval; NA = not available (could not be estimated); OMBP = oral mechanical bowel preparation; OR = odds ratio

Note: The solid squares (and horizontal lines) indicate the point estimate of the OR (and the corresponding 95% CI) for individual studies; the diamonds (and horizontal lines) indicate the summary estimate of the OR (and the corresponding 95% central CrI). The numbers of events and the sample size of each treatment group are shown to the right of the plot. The dashed line indicates an OR of 1.

Reoperation

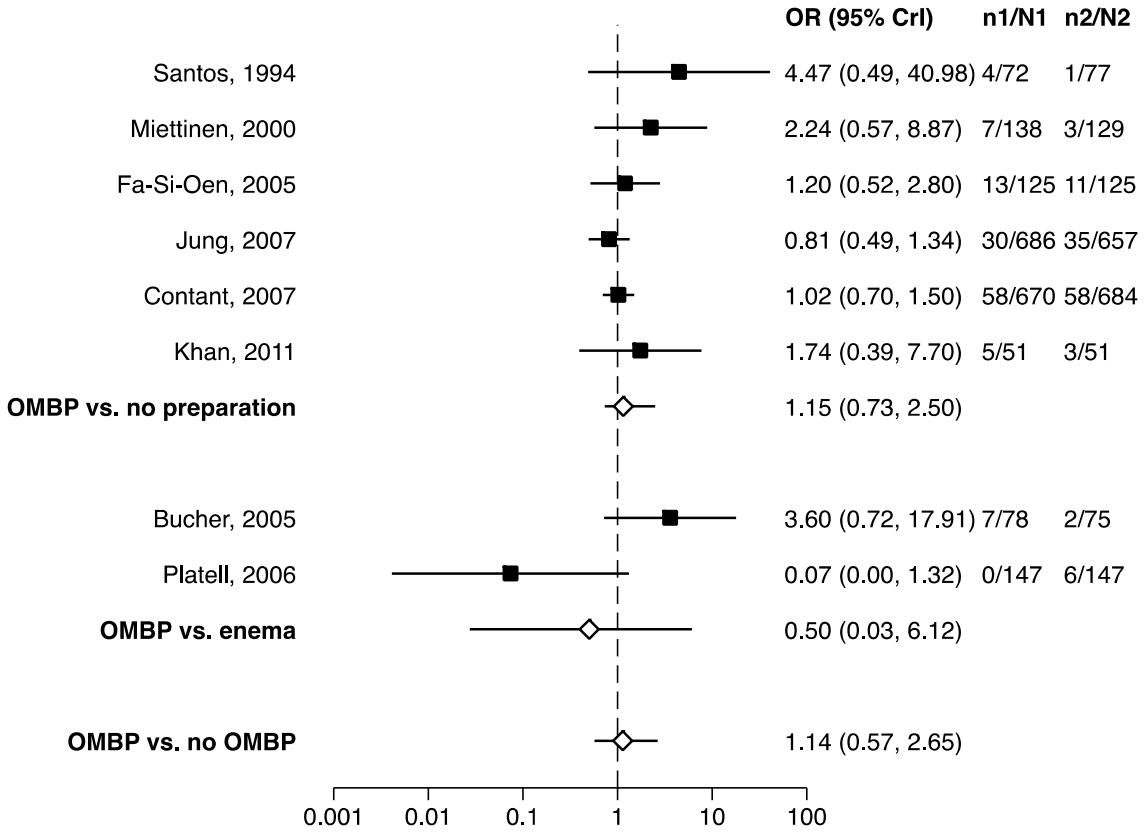
OMBP Versus No Preparation

Six RCTs comparing OMBP versus no preparation reported information on reoperation; all studies reported the occurrence of at least one outcome event. Studies had varying sample sizes (minimum = 149; maximum = 1354) and reported a total of 228 events. The summary OR for reoperation was 1.15 (95% CrI 0.73 to 2.50). There was little evidence of between-study heterogeneity but there was substantial uncertainty for this parameter: the posterior distribution of the between-study variance of the log-OR had a median of 0.09 (95 CrI, 0 to 1.82). Figure 9 presents the meta-analysis results, along with study-specific event rates.

OMBP Versus Enema

Two RCTs comparing OMBP versus enema reported information on reoperation; both studies reported the occurrence of at least one outcome event. Studies were relatively small (sample sizes were 154 and 294) and reported a small number of outcome events (15 events total). The summary OR for reoperation was 0.50 (95% CrI 0.03 to 6.12). However, the estimate was extremely imprecise, reflecting the small number of patients contributing information to the meta-analysis, the very small number of observed events. There was little evidence of between-study heterogeneity but there was substantial uncertainty for this parameter: the posterior distribution of the between-study variance of the log-OR had a median of 2.49 (95 CrI, 0.27 to 3.93). Figure 9 presents the meta-analysis results, along with study-specific event rates.

Figure 9. Reoperation meta-analysis results for studies comparing OMBP (with or without enema) versus no preparation or enema



CI = confidence interval; CrI = credible interval; NA = not available (could not be estimated); OMBP = oral mechanical bowel preparation; OR = odds ratio

Note: The solid squares (and horizontal lines) indicate the point estimate of the OR (and the corresponding 95% CI) for individual studies; the diamonds (and horizontal lines) indicate the summary estimate of the OR (and the corresponding 95% central CrI). The numbers of events and the sample size of each treatment group are shown to the right of the plot. The dashed line indicates an OR of 1.

Surgical Site Infections

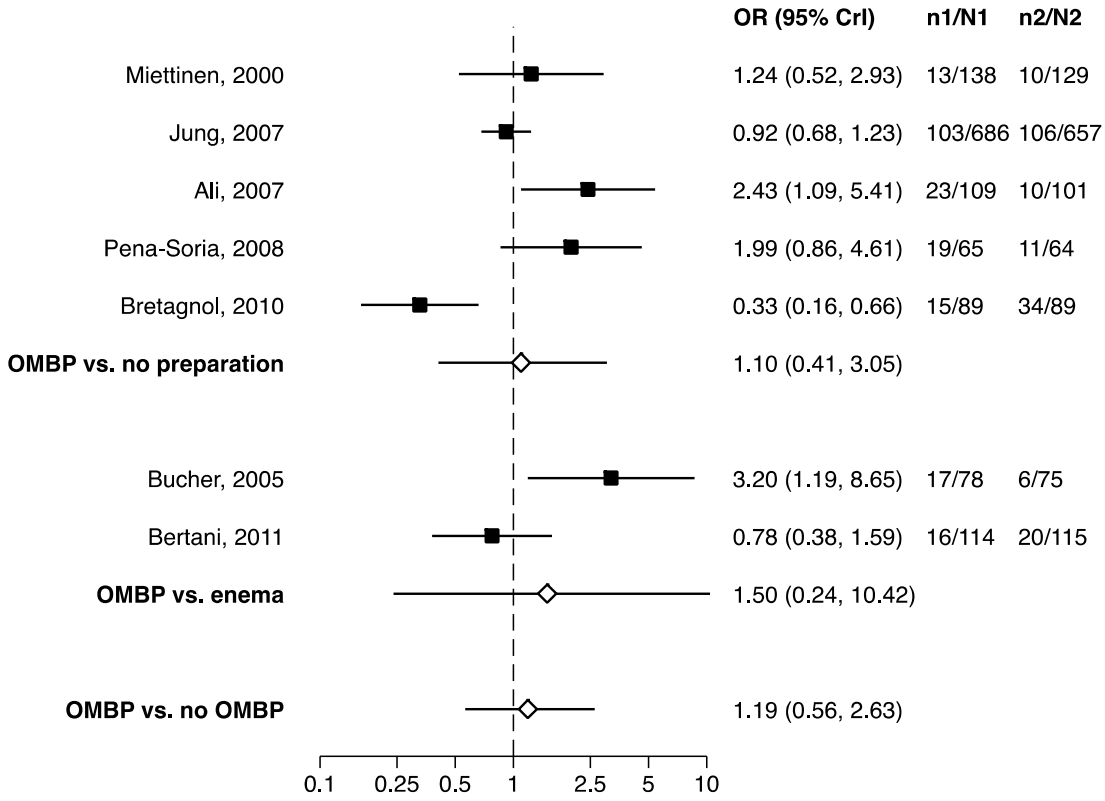
OMBP Versus No Preparation

Five RCTs comparing OMBP versus no preparation reported information on infectious complications classified as surgical site infections; all studies reported the occurrence of at least one outcome event. Studies had varying sample sizes (minimum = 129; maximum = 1343) and reported a total of 344 events. The summary OR for SSI, comparing OMBP-treated patients versus controls was 1.10 (95% CrI 0.41 to 3.05). However, the estimate was somewhat imprecise, reflecting the relatively small number of studies contributing information to the meta-analysis. There was some evidence of between-study heterogeneity but there was substantial uncertainty for this parameter: the posterior distribution of the between-study variance of the log-OR had a median of 0.76 (95 CrI, 0.10 to 3.39). Figure 10 presents the meta-analysis results, along with study-specific event rates.

OMBP Versus Enema

Two RCTs comparing OMBP versus enema reported information on surgical site infections. Studies were small (sample sizes of 153 and 229) and reported a small number of outcome events (59 events total). The summary OR for surgical site infections was 1.50 (95% CrI 0.24 to 10.42). However, the estimate was very imprecise, reflecting the relatively small number of patients contributing information to the meta-analysis, the small number of observed events, and the presence of substantial between-study heterogeneity: the posterior distribution of the between-study variance of the log-OR had a median of 1.20 (95 CrI, 0 to 3.79). Figure 10 presents the meta-analysis results, along with study-specific event rates.

Figure 10. Surgical site infection meta-analysis results for studies comparing OMBP (with or without enema) versus no preparation or enema



CI = confidence interval; CrI = credible interval; NA = not available (could not be estimated); OMBP = oral mechanical bowel preparation; OR = odds ratio

Note: The solid squares (and horizontal lines) indicate the point estimate of the OR (and the corresponding 95% CI) for individual studies; the diamonds (and horizontal lines) indicate the summary estimate of the OR (and the corresponding 95% central CrI). The numbers of events and the sample size of each treatment group are shown to the right of the plot. The dashed line indicates an OR of 1.

Venous Thromboembolism (Deep Venous Thrombosis and Pulmonary Embolism)

OMBP Versus No Preparation

Three studies comparing OMBP versus no preparation reported information on venous thromboembolic outcomes (1 study reported information on pulmonary embolism, 1 study on

venous thrombosis, and 1 on both outcomes). None of the comparisons were statistically significant, and study-specific estimates of effect were very imprecise. Thus, no clinically meaningful conclusions could be reached.

OMBP Versus Enema

No studies comparing OMBP versus enema reported information on venous thromboembolic outcomes.

Length of Hospital Stay

OMBP Versus No Preparation

Nine studies comparing OMBP versus no preparation reported information on mean or median length of hospital stay (6 studies on total and 3 studies on postoperative length of stay), but did not report information to enable statistical testing. The difference in mean or median length of stay between groups ranged from -5 days to 4.4 days and was positive in four studies, negative in two studies, and (reported as) exactly zero in two studies (positive values indicate longer average length of stay for patients in the OMBP-treated group). Statistical comparisons of the duration of stay were possible only in five of the studies (3 reporting on total length of stay and 2 reporting on postoperative stay); differences were statistically non-significant in one study (longer total duration in the OMBP-treated group).

OMBP Versus Enema

Three studies comparing OMBP versus enema reported information on mean or median total length of hospital stay (no studies reported information separately for the pre- and postoperative periods), but did not report information to enable statistical testing. The difference in mean or median length of stay ranged from 0.1 days to 0.9 days (and was positive in all studies).

Patient Satisfaction and Quality of Life

No studies reported information on patient satisfaction and quality of life using appropriate measurement scales. However, several studies assessed patient-relevant symptoms (e.g., nausea, discomfort, malaise, etc.) using ordinal scales. Findings from these studies have been summarized in Key Question 2.

Other Outcomes

No studies provided information on other prespecified effectiveness outcomes for this Key Question (unplanned ostomies, failed attempts to restore bowel continuity, readmissions after surgery, additional interventional procedures (other than surgery); admission to intensive care unit, admission to nursing care).

Sensitivity Analyses

For mortality, anastomotic leakage, and wound infection we reanalyzed the available data after (1) excluding two studies[76,81] that included both adults and children (and did not report results separately by age group); (2) excluding one study[55] that was unclearly reported and had been presented as a conference paper published in a peer-reviewed journal (this study was also excluded from a recent Cochrane review on OMBP); (3) including the one study[78] that has been retracted; (4) excluding studies using selective enema strategies in their control groups[38,93] (in

main analyses, we included studies using enemas for patients undergoing rectal surgery only together with studies using enema on all patients, because we reasoned that this is the subgroup of patients most likely to experience any effects from enema use). The complete results of these sensitivity analyses are presented in Appendix C. These analyses produced results that were consistent with our main analyses (presented above).

We also examined whether our results were robust to the choice of alternative analysis methods. Appendix D presents sensitivity analyses for Bayesian pairwise meta-analyses with respect to the choice of alternative prior distributions for the between-studies variance parameter. Appendix E presents results of frequentist (non-Bayesian) analyses for all outcomes and all comparisons presented in the preceding section. Overall, none of these analyses produced results that were qualitatively different from those our main analyses (presented above).

Risk of Bias Assessment for Individual Studies

Information on trial design needed to assess the risk of bias of individual studies was not fully reported. For example, among the 18 RCTs comparing OMBP versus no OMBP, information on randomized sequence generation and allocation concealment was deemed "unclear" in eight and 10 studies, respectively. In addition, blinding of patients, care providers, and outcome assessors was unclear in 14, 10, and 12 of the studies, respectively. In contrast, information on withdrawals and dropouts was better reported. Of the studies reporting relevant information, only two reported a dropout rate of more than 10 percent (both only in their no-OMBP trial groups) and no study had evidence of differential dropout (defined as a greater than 10 percent difference in the dropout rate between treatment groups). Overall, based on the number of items considered indicative of Low risk, eight studies were considered to be at high risk of bias, nine to be at intermediate risk of bias, and one to be at low risk of bias. As always, aggregated risk of bias assessments need to be interpreted with caution, given our inability to fully distinguish inappropriate study design from poor reporting and lack of context-specific evidence that the risk items we assessed are indeed associated with bias.

Association of Anatomic Location and Study Characteristics (Including Risk of Bias Items) With OMBP Effectiveness

We investigated whether the effect of OMBP varied by anatomic location (colon versus rectum), year of publication, or items related to study risk of bias (specifically, randomized sequence generation and allocation concealment).

Anatomic Location

Using published data and information obtained though author contact, separate analyses by anatomic location were possible for the outcome of anastomotic leakage (data were insufficient for other outcomes). There was limited evidence of effect modification by anatomic location; however, summary estimates were imprecise and evidence was available only from 10 studies (11 publications) that used heterogeneous subgroup definitions. The OR for anastomotic leakage comparing OMBP versus enema or no preparation was 1.01 (95% CrI, 0.57 to 2.13) for colon surgery (9 studies); and 0.91 (95% CrI, 0.42 to 2.45) for rectal surgery (7 studies; 6 studies provided information for both subgroups).

Year of Study Publication

In meta-regression analyses comparing OMBP versus enema or no preparation (Table 4) over year of publication, the 95% CrI of the relative OR included the null value; however, CrIs were wide, indicating substantial uncertainty regarding changes in treatment effectiveness over time. Thus, definitive conclusions about the presence of temporal trends could not be drawn.

Risk of Bias Items

In meta-regression analyses comparing OMBP versus enema or no preparation over randomized sequence generation (Table 4), the 95% CrI of the relative OR included the null value for all key outcomes with 10 or more available studies. However, CrIs were wide, indicating substantial uncertainty regarding differences across studies.

For allocation concealment the OR comparing OMBP versus enema or no preparation was lower in trials considered at low risk of bias compared to trials at higher or unclear risk. Specifically, trials with adequate allocation concealment methods suggested that OMBP has a protective effect (i.e., OR <1); whereas trials with inadequate or unclear allocation concealment methods had a summary effect in the opposite direction (i.e., OR>1) (Table 4). Clearly, appropriate (and well-reported) procedures of allocation concealment are preferable in any clinical trial. However, we caution against interpreting our result as "proof" for the presence of bias because the reporting of allocation concealment was incomplete in the reviewed studies, other study characteristics that may be associated with allocation concealment methods (and reporting) could not be accounted for in the analysis, the association was observed only for one of the outcomes of interest (and in one of several regression analyses), and the relative OR was extreme and fairly imprecise. Of note, in the low risk of bias subgroup of studies the CrI of the OR comparing OMBP versus enema or no preparation for anastomotic leakage included the null value; OR = 0.81 (95% CrI, 0.56 to 1.19). These findings in conjunction with the wide credible intervals observed in the overall meta-analysis support the need for more research.

Other risk of bias items were poorly reported and did not show adequate variation across studies; for this reason they were not considered in meta-regression analyses.

Table 4. Meta-regression results for studies comparing OMBP (with or without enema) versus enema or no preparation

Potential Modifier	Outcome	rOR (95% CrI)
Year of publication (per decade)	All-cause mortality	0.79 (0.38 to 1.55)
	Anastomotic leakage	0.80 (0.41 to 1.65)
	Wound infection	1.00 (0.73 to 1.41)
ROB for randomized sequence generation (low vs. moderate/high/unclear)	All-cause mortality	0.35 (0.08 to 1.52)
	Anastomotic leakage	0.71 (0.36 to 1.50)
	Wound infection	0.91 (0.51 to 1.73)
ROB for allocation concealment (low vs. moderate/high/unclear)	All-cause mortality	0.90 (0.24 to 3.88)
	Anastomotic leakage	0.45 (0.23 to 0.85)
	Wound infection	0.64 (0.38 to 1.08)

CrI = credible interval; ROB = risk of bias; rOR = relative odds ratio; SSI = surgical site infection
Note: Results suggestive of an association are highlighted in bold type.

Direct Comparisons of OMBP Versus No OMBP in NRCSs

Seven NRCSs reported information on the comparison of OMBP versus omission of preparation. Because of heterogeneity in patient selection and outcomes reported, differences in study design, and concerns regarding risk for residual confounding we did not perform meta-analysis.

One study[74] reported an experimental[h] nonrandomized comparison of OMBP (165 patients, all treated with sodium phosphate) versus no preparation (164 patients) in patients undergoing elective colorectal surgery in a single center. Assignment to treatments was based on patients' identification numbers, offering some protection from confounding bias. The study found no statistically significant difference between the two groups for the outcomes of all-cause mortality, wound dehiscence, wound infection, anastomotic leakage, thrombophlebitis, or the need for repeat laparotomy. Events were more common in the OMBP group for all outcomes except anastomotic leakage and thrombophlebitis. For all outcomes, estimates of effect were very imprecise and no between-group difference was statistically significant. The study was considered to be at moderate risk of bias because of lack of randomization, allocation concealment, or blinding of care providers and outcome assessors.

Another study[53] reported an observational comparison of anastomotic leakage rates among patients treated at a single center before (1997–2002) and after (2002–2006) the implementation of a policy of omitting OMBP (in the first period patients were treated with bisacodyl and sodium phosphate). The authors noted that another change in treatment policy occurred during the study period: a replacement of ibuprofen by celecoxib (for the years between 2003 and 2004). The rates of anastomotic leakage were 3.5 percent (7 of 203 patients) versus 1.7 percent (3 of 180 patients) during the period of OMBP plus celecoxib and no OMBP no celecoxib preparation (P = 0.35). Results for the other treatment periods were not reported and the study was considered to be at high risk of bias because historical comparisons were unadjusted for potential confounding factors (particularly those that vary over time).

The third study[63] reported results from an observational analysis of 2263 patients undergoing nonemergent colectomy in 24 hospitals participating in the Michigan Surgical Quality Collaborative Colectomy project. A total of 1685 patients received OMBP (oral cathartics with or without enema; in 684 patients combined with oral antibiotics and in 1001 without), and 578 did not; the study outcome was the development of *Clostridium difficile* infection. The adjusted OR comparing OMBP-treated versus not treated patients was 0.96 (95% CI 0.50 to 1.83) and was not-statistically significant. Among patients who received OMBP, the use of oral antibiotics was associated with a statistically nonsignificant reduction in the odds of *Clostridium difficile* infection (OR = 0.60; 95% CI 0.29 to 1.23). The study was considered to be at high risk of bias because of concerns about residual confounding (factors that differed between treated groups at baseline, and other potential confounders, may not have been included in the multivariable analysis because of the variable selection method employed).

The fourth study[60] also used data from the Michigan Surgical Quality Collaborative Colectomy project to compare OMBP with oral antibiotics versus no OMBP (with or without oral antibiotics); patients receiving OMBP without oral antibiotics were excluded. Using propensity score methods, 957 treated patients were matched with an equal number of untreated patients (1:1 matching). In matched-pair analyses, OMBP with oral antibiotics was associated with a lower incidence proportion of organ space (1.57% versus 3.13%; P=0.024), superficial (2.93% versus 5.96%%; P=0.001), and overall surgical site infections (5.02% versus 9.72%; P<0.001), but not deep incisional infections (0.73% in both groups; P=0.99). The study was deemed to be at moderate risk of bias; even though matching was performed for a fair amount of variables some important variables were not considered (e.g., the type of surgical operation or its

[h]Experimental indicates that the investigators had control over treatment assignment (i.e., patients did not self-select into treatments). However, treatment assignment was deterministic (based on patient's identification numbers).

anatomic location). In addition, because of the design of the study, the effect of OMBP could not be identified from that of oral antibiotics.

The fifth study[40] reported results from an observational retrospective analysis of data from the Veterans Affairs Surgical Quality Improvement Program, using the Veterans Affairs Surgical Care Improvement Project and Pharmacy Benefits Management data to evaluate the impact of OMBP on surgical site infections within 30 days of elective colorectal surgery. The study included a total of 9940 patients (1978 received no preparation; 723 received oral antibiotics only; 3839 receive OMBP only; and 3400 received OMBP and oral antibiotics). OMBP strategies included polyethylene glycol, sodium phosphate, and magnesium citrate. In multivariable analyses (including 6070 patients), using the no preparation as the baseline, the OR for surgical site infection was 0.33 (95% CI 0.21 to 0.50); 0.99 (95% CI 0.80 to 1.22); and 0.43 (95% CI 0.34 to 0.55), for patients receiving oral antibiotics, OMBP without antibiotics, and OMBP plus oral antibiotics, respectively. The study was considered to be at moderate risk of bias because of concerns regarding residual confounding (a limited number of covariates were controlled in the analysis).

The sixth study[82] also used results from the Veterans Affairs Surgical Quality Improvement Program to evaluate the impact of OMBP for colorectal surgery on length of stay and re-admission within 30 days of the operation. The study included a total of 8180 patients (1412 received no preparation; 3193 received OMBP alone; and 3575 received oral antibiotic preparation, with or without OMBP; the later group was not further stratified by OMBP use). In analyses adjusted for indication for surgery, age, procedure type, ostomy, American Society of Anesthesiologists class, and wound class, use of OMBP (without oral antibiotics) was associated with reduced length of stay; the number of hospitalization days was approximately 3.5% lower compared to no preparation; P=0.023. Use of oral antibiotic preparation (with or without OMBP) was also associated with reduced length of stay; the number of hospitalization days was 11% lower compared to no preparation; P<0.001. In analyses of readmission within 30 days, adjusted for the same variables as the analyses of length of stay, oral antibiotic preparation (with or without OMBP) was associated with reduced odds of readmission (OR=0.81; 95% CI, 0.68 to 0.97). In contrast, OMBP alone was not associated statistically significantly with the odds of readmission (OR=0.96; 95% CI, 0.81 to 1.15). The study was considered to be at moderate risk of bias because of concerns regarding residual confounding.

The seventh study[69] reported results using clinical audit data from the West of Scotland Colorectal Cancer Managed Clinical Network, and death records from the Scottish Cancer Registry and General Register Office of Scotland. The study included a total of 1730 patients (1460 received OMBP and 270 did not). In multivariable analyses, the OR for mortality comparing OMBP-treated versus non-treated patients was 0.85 (95% CI 0.67 to 1.10); P = 0.22; at a mean followup of 3.5 years. In unadjusted analyses of 30-day postsurgical outcomes, there was no statistically significant difference between groups for anastomotic leakage, intra-abdominal abscess, fistula, would infection, deep venous thrombosis, pulmonary embolism, chest infection, or a composite of any postoperative complication. The study was considered to be at moderate risk of bias on the basis of concerns about residual confounding and because some of the comparisons between treatment groups were not adjusted for potential confounders.

Overall, the NRCSs reported results consistent with those of RCTs and did not demonstrate significant differences between OMBP and no-OMBP strategies. However, studies were at substantial risk of bias, mostly due to confounding factors that had not been adequately controlled in the design or analysis of these investigations.

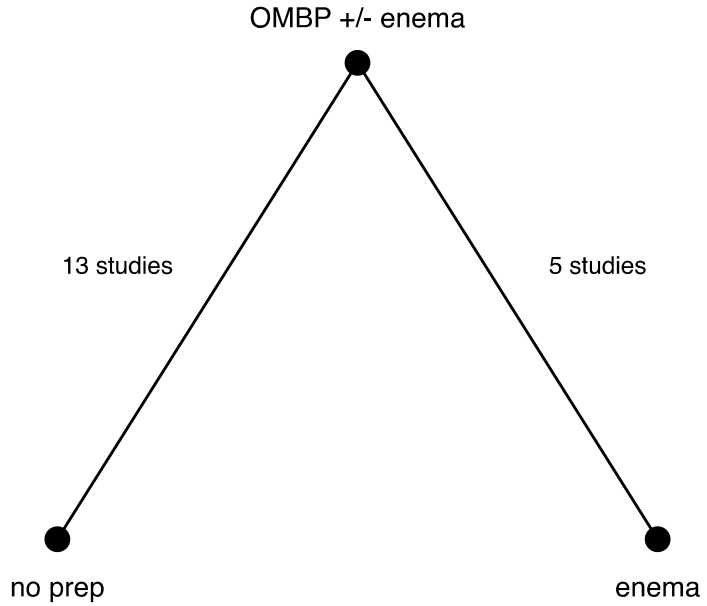
Network Meta-Analysis

To further explore the available data on the effectiveness of OMBP, as compared to enema or no preparation, we analyzed the data presented in the previous section using Bayesian network meta-analysis of the 18 RCTs comparing OMBP versus enema or no preparation. The underlying model respects the randomization procedure within each study and allows us to borrow strength across different direct comparisons when estimating between-study heterogeneity. See the Methods section for additional information on the network structure and details of the statistical analysis.

Comparative Effectiveness of OMBP, Enema, and No Preparation

Our main analysis used 3-node network structure (topology) comparing OMBP (with or without enema) versus enema alone and versus no preparation. Figure 11 presents the structure of the network. Estimates of the comparative effectiveness of enema versus no preparation can only be obtained via indirect comparisons (because no trials directly comparing these two interventions were included in our analyses), and are not shown.

Figure 11. Three-node network structure



No prep = no OMBP and no enema; OMBP = oral mechanical bowel preparation
Note: Structure for the 3-node network meta-analysis comparing OMBP +/- enema vs. enema alone vs. no preparation. Nodes indicate the treatments compared. Connecting lines depict direct comparisons and are labeled with the total number of available studies (not all studies contributed data for all outcomes).

Table 5 summarizes the results of this analysis, for all the possible pairwise comparisons, for outcomes where enough studies were available. Generally, results are consistent with those of the direct comparisons reported in the preceding section: 95% credible intervals do not exclude the null value for any outcome.

Table 5. Summary estimates from the three-node network meta-analysis

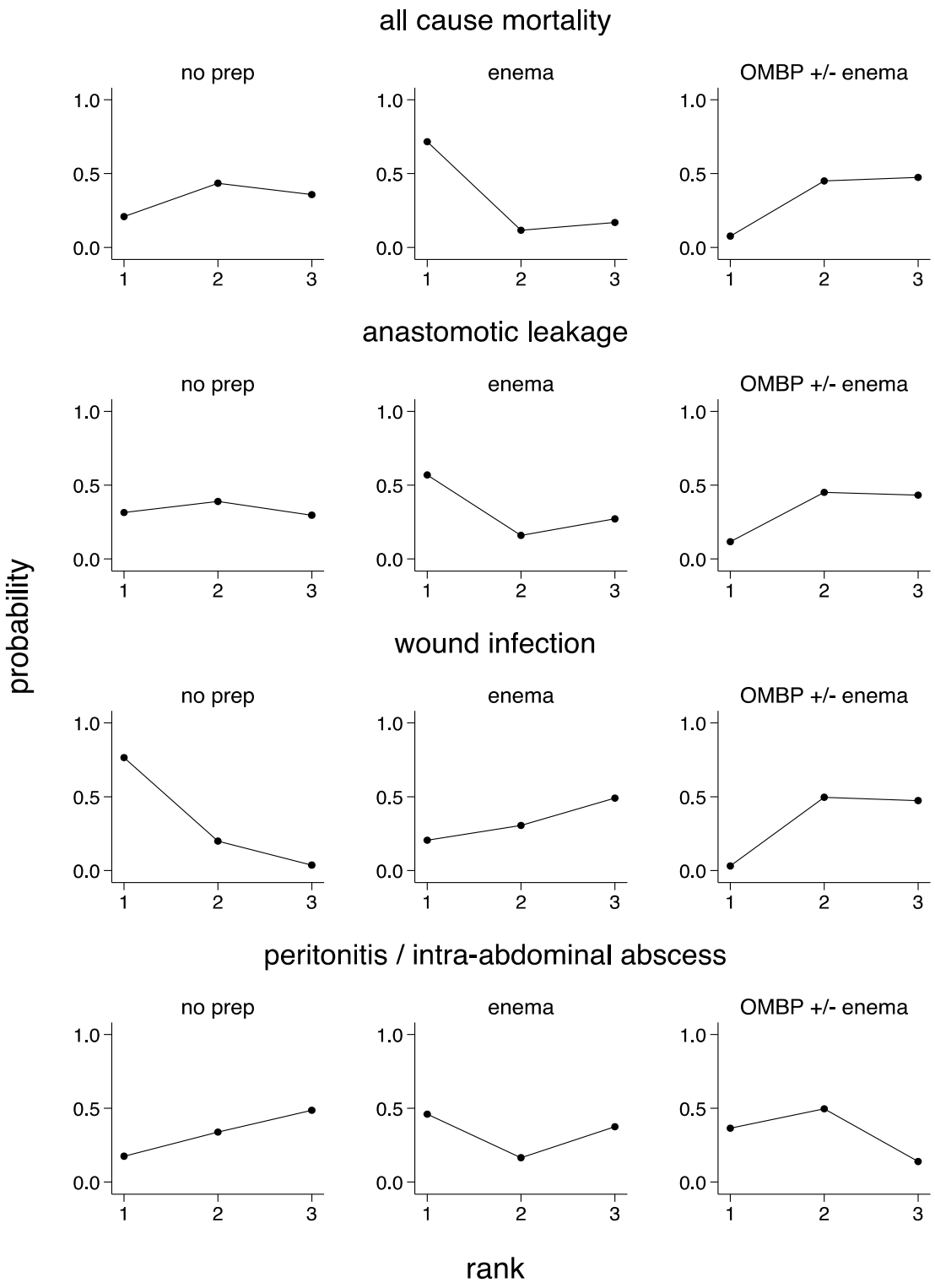
Outcome	Comparison	OR (95% CrI)
All-cause mortality	OMBP ± enema vs. no prep	1.08 (0.56 to 3.02)
	OMBP ± enema vs. enema	1.88 (0.40 to 10.56)
Anastomotic leakage	OMBP ± enema vs. no prep	1.07 (0.73 to 1.73)
	OMBP ± enema vs. enema	1.20 (0.57 to 2.61)
Wound infection	OMBP ± enema vs. no prep	1.27 (0.94 to 1.91)
	OMBP ± enema vs. enema	1.00 (0.59 to 1.76)
Peritonitis/intra-abdominal abscess	OMBP ± enema vs. no prep	0.82 (0.46 to 1.82)
	OMBP ± enema vs. enema	0.99 (0.24 to 4.07)

CrI = credible interval; no prep = no OMBP and no enema; OMBP = oral mechanical bowel preparation; OR = odds ratio
Note: OR values lower than 1 indicate that events are less common among treatment groups receiving the first listed treatment for each comparison. Results based on indirect comparisons were imprecise and are not shown.

Rank Probabilities

Using the network structure presented in Figure 11 we estimated the probability of a given treatment to be the best (i.e., to be associated with the lowest incidence of harmful events, rank = 1), second best (rank = 2), or last (rank = 3) with respect to each of four key outcomes of interest: all-cause mortality, anastomotic leakage, wound infection, and peritonitis or intra-abdominal abscess (Figure 12). The rank probabilities take into account the difference in the point estimates of the treatment effects and the uncertainty around them. However, they do not readily convey the difference in the treatment effects and they have to be interpreted with caution. Overall, across outcomes, no one intervention appears to be uniformly better or worse than the others.

Figure 12. Ranking of treatments based on the 3-node network meta-analysis



No prep = no OMBP and no enema; OMBP = oral mechanical bowel preparation
Each panel depicts the estimated probability that a given treatment is the best (rank = 1), second best (rank = 2), or last (rank = 3), for each of the outcomes of interest. Probabilities across ranks (within a treatment) and probabilities of the same rank (across treatments) sum to 1.

Probability of Differences Above Threshold Values

We also estimated the probability that the true OR comparing pairs of interventions was above or below some threshold. These results are summarized in Table 6**.** Note the substantial uncertainty around summary estimates: although very extreme OR values (i.e., below 0.5 and above 3) are quite unlikely for all outcomes, values less than 0.8 or greater than 1.25, corresponding to a decrease of 20 percent or an increase of 25 percent in the odds of an event, are not unlikely for almost all outcomes.

Table 6. Probability that the treatment effect is smaller (or larger) than various cut-off values, for each outcome of interest

Outcome	Comparison	Probability That the OR is Smaller Than (or Exceeds) a Threshold Value												
		<0.2	**<0.333**	**<0.5**	**<0.667**	**<0.80**	**<0.91**	**>1**	**>1.10**	**>1.25**	**>1.5**	**>2**	**>3**	**>5**
All-cause mortality	OMBP vs.no prep	0	0	0.01	0.07	0.17	0.3	0.59	0.48	0.34	0.2	0.08	0.03	0.01
	OMBP vs. enema	0.01	0.02	0.04	0.08	0.13	0.16	0.8	0.77	0.71	0.62	0.47	0.27	0.11
Anastomotic leakage	OMBP vs.no preparation	0	0	0	0.01	0.07	0.2	0.63	0.44	0.22	0.07	0.01	0	0
	OMBP vs. enema	0	0	0.01	0.06	0.14	0.22	0.69	0.59	0.45	0.27	0.09	0.01	0
Wound infection	OMBP vs.no prep	0	0	0	0	0	0.02	0.94	0.82	0.54	0.18	0.02	0	0
	OMBP vs. enema	0	0	0.01	0.06	0.19	0.35	0.5	0.36	0.2	0.07	0.01	0	0
Peritornitis/ intra-abdominal abscess	OMBP vs.no prep	0	0	0.05	0.24	0.46	0.62	0.28	0.2	0.12	0.06	0.02	0	0
	OMBP vs. enema	0.01	0.06	0.16	0.28	0.38	0.45	0.49	0.44	0.37	0.27	0.16	0.06	0.01

No prep = no OMBP and no enema; OMBP = oral mechanical bowel preparation; OR =odds ratio

Note: "0" should be interpreted as very low probability (because the probability cannot be exactly zero).

Analysis of a Structural Variant of the Network

Appendix F presents the results of structural sensitivity analysis for the network meta-analysis. Appendix Figure F1 shows the topology of the structural variant of the network. Overall, the results of this sensitivity analysis (Appendix Table F1) are consistent with those based on the 3-node network model (Table 5): although there is even greater uncertainty regarding the comparative effectiveness of the available interventions than under the previous two models. This is particularly true for rare outcomes (e.g., mortality) and for comparisons without head to head data. Therefore the analysis did not lead to definitive conclusions regarding the effect of adding enema to OMBP.

Comparisons of Alternative Active OMBP Strategies

For the reasons outlined in the beginning of the Results chapter, studies comparing alternative active OMBP strategies were considered separately from those reporting on comparisons between OMBP and no OMBP strategies.

Twenty-three RCTs and two NRCSs provided information on comparisons among active OMBP strategies for adult patients undergoing elective colorectal surgery. We first examine the findings of RCTs, followed by the findings of NRCSs.

RCTs Comparing Alternative OMBP Strategies

Twenty-one of the 23 RCTs enrolled primarily adult patients and two enrolled exclusively children. The most common indications for surgery were colorectal cancer and diverticular disease. Two studies enrolled only patients diagnosed with cancer. Eight studies excluded patients with inflammatory bowel disease. Details on the surgical approach (e.g., operation types, anastomosis methods, open versus laparoscopic surgery) were generally not reported. Information on the breakdown of surgical sites into right colon, left colon and rectum was generally not reported. Most studies enrolled mixed populations of patients undergoing colon and rectal surgery, but none reported outcome data separately by anatomic location. One study enrolled exclusively patients undergoing left colon or rectal surgery. No study enrolled exclusively patients undergoing rectal surgery.

We grouped OMBP strategies in the active versus active studies into seven grand categories to facilitate synthesis and presentation, as described in the Methods section: PEG, hyperosmotic sodium solutions, other laxatives or cathartics, PEG and laxatives/cathartics, whole gut irrigation, mixed/other, and dietary interventions. The most common comparisons were between PEG- versus whole-gut-irrigation-based OMBP (examined in 5 RCTs) and PEG-based versus laxative/cathartic-based OMBP (6 RCTs). Note that we were lenient in the grouping of OMBP interventions in the seven categories, and that the actual interventions in RCTs that are grouped in the same category can be quite diverse.

The majority of RCTs (19 out of 23) had two treatment groups; three had three groups and one had four groups, for a total of 51 active OMBP groups and 34 possible pairwise contrasts. Studies compared diverse OMBP strategies: of the 51 groups, 12 received PEG solutions, 16 laxatives or cathartics (mainly, senna or bisacodyl), three hyperosmotic sodium solutions, three a combination of PEG with laxatives or cathartics, 10 whole gut irrigation with electrolyte solutions other than PEG (typically Ringer's lactate or normal saline), three combinations of these strategies or other OMBP drugs, and four nutritional interventions (prebiotics or symbiotics).

Many items necessary for detailed assessment of all risk of bias were unreported in most studies. Overall, based on the number of items considered indicative of low risk, 10 studies were considered to be at high risk of bias, 12 to be at intermediate risk of bias, and one to be at low risk of bias. Details on the risk of bias are given at the end of this subsection.

Summary of Findings From RCTs Comparing Active OMBP Strategies

We did not perform meta-analysis of findings from head-to-head (active versus active) studies of OMBP strategies, because of extensive diversity of the employed OMBP strategies, the heterogeneity in the assessed outcomes, and, of concerns regarding selective outcome reporting (and other risk of bias dimensions). Instead, we summarize the information extracted from studies in a series of graphs (Figure 13). The underlying data, together with additional extracted information are accessible online (at http://srdr.ahrq.gov/).

We use the first page of Figure 13 as an example. Each panel summarizes information on one outcome. The left upper panel shows information on overall mortality. Each outcome panel is a matrix of cells that represent contrasts between the strategies listed in the rows versus the strategies in the columns. Markers are plotted in a cell if an actual study compared the respective strategies. Marker color and shape is a key to whether the outcome was reported, and if so, to the direction and significance of the treatment effects:

- **Gray 'x' markers** denote that a study did not assess the predefined outcome, or if it did assess it, it did not report sufficient data for a meta-analysis.
- **Gray hollow markers** denote that the effects in the first (row) versus the second (column) strategy were statistically not significant (P-value $\geq$0.05).
    - **Gray hollow circles** stand for studies where effects trend in favor of the row versus the column strategy.
    - **Gray hollow triangles** stand for studies where there is no effect (e.g., equal number of events in each arm).
    - **Gray hollow squares** stand for studies where effects trend in favor of the column versus the row strategy.
- **Black hollow markers** denote that the effects were statistically significant at the P <0.05. The corresponding marker shapes (as for nonsignificant findings) denote the direction of the effects.

Consider the top left panel in the first page of Figure 13. For the outcome of all-cause mortality, a single grey 'x' marker in the cell at the intersection of hyperosmotic sodium solution-based strategy (4th column) and laxatives/cathartics (2nd row) indicates that a single study compared these two OMBP strategies, but this study reported no analyzable results on all-cause mortality. Also, whole gut irrigation (WGI) was associated with reduced incidence of death compared to laxatives/cathartics, but the difference was not statistically significant at the 0.05 level.

Figure 13 allows us to make the following observations:

Only 13 out of the 28 cells (comparisons) have some empirical information, i.e., have at least one study (one marker). This density of observed versus possible comparisons is somewhat optimistic: we have been quite lenient in categorizing the individual active OMBP comparisons into the seven conceptual categories represented by rows and columns in each panel. If we used a more granular categorization, the matrix would be larger, and there would be fewer studies in each of the cell. Further, we have also been lenient in the categorization of outcomes. For example, we operationalized peritonitis (lower right panel in the first page in Figure 14) as a

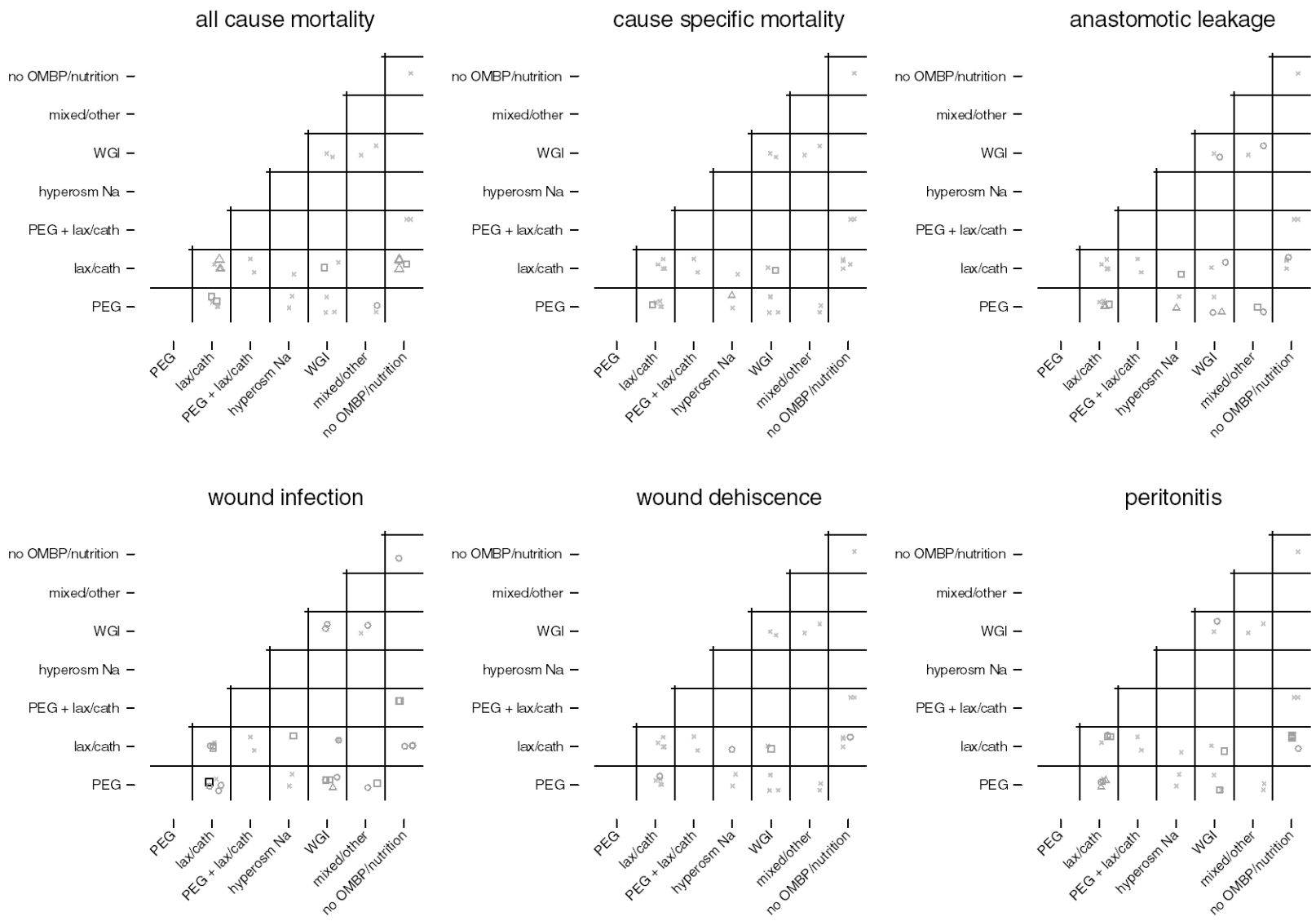
clinical diagnosis defined by the study authors as a condition (local or generalized) that warrants repeat surgery, or deep infection or abscess.

Outcomes are assessed or reported in sufficient detail in a minority of the conducted studies, perhaps with the exception of wound infection in Figure 13. Where two or more studies provided information for the same outcome (e.g., wound infection) no conclusions could be reached regarding the comparative effectiveness of interventions. **Some of the outcomes of interest to this review, such as pulmonary embolism, and venous thrombosis were not reported in any study.**

Visually, most markers in each panel are grey x's, and just a handful are hollow (grey or black). The empirical evidence that is available to a literature-based review is but a small fraction of what could have been available. This represents a lost opportunity. If the observed outcomes are missing at random (e.g., by design) or completely at random, the missingness is ignorable, and represents loss of precision in the estimates we get from these studies. If, however, information is censored for systematic reasons (e.g., because of selective outcome reporting[95,96]), then summaries of the published literature are likely misleading. We have no solid indications of outcome reporting bias in this set of studies. As discussed in the risk of bias subsection, however, one is left with the impression that a lot in their design, conduct and analysis could be done better.

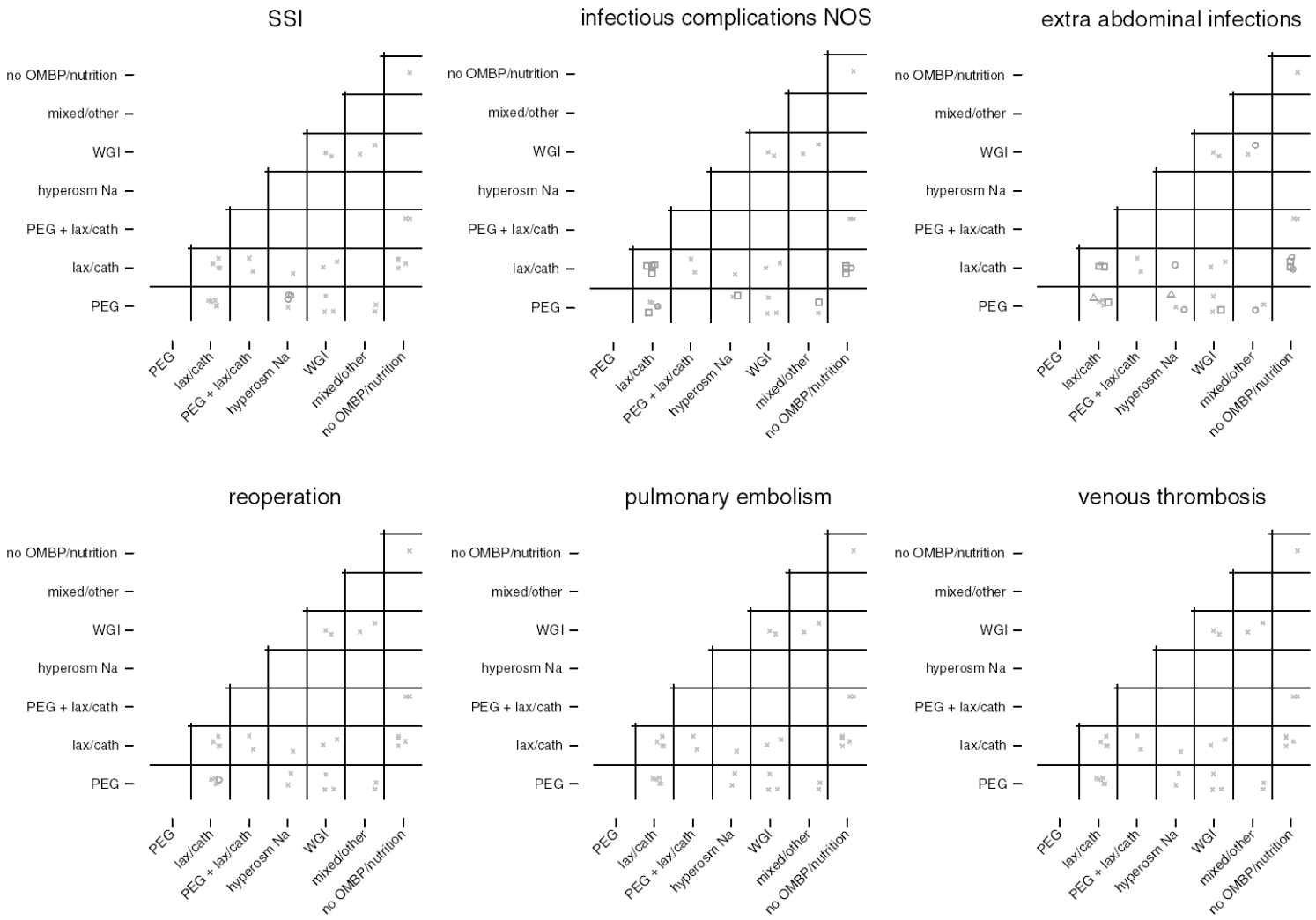
The majority of the available studies are small, and probably underpowered to detect modest or small effect sizes, let alone relatively rare harms. Across all 106 analyzable results (outcome/comparison combinations) two were statistically significant –visually, in the three Figures the gray hollow markers far outnumber the black ones. This proportion (2%) is less than the 5% that would be expected by chance if the null hypothesis of no association were true. Because the true distribution of effects in this body of literature is unknown, and because these analyses are not independent (per study, they are in the same patients), one cannot simply infer that all identified statistically significant findings are false. Nevertheless, this observation may suggest that studies were underpowered to detect modest treatment differences or that very few, if any, genuine differences exist among active OMBP strategies in the included studies.

Figure 13. Summary of findings from studies comparing alternative active OMBP strategies



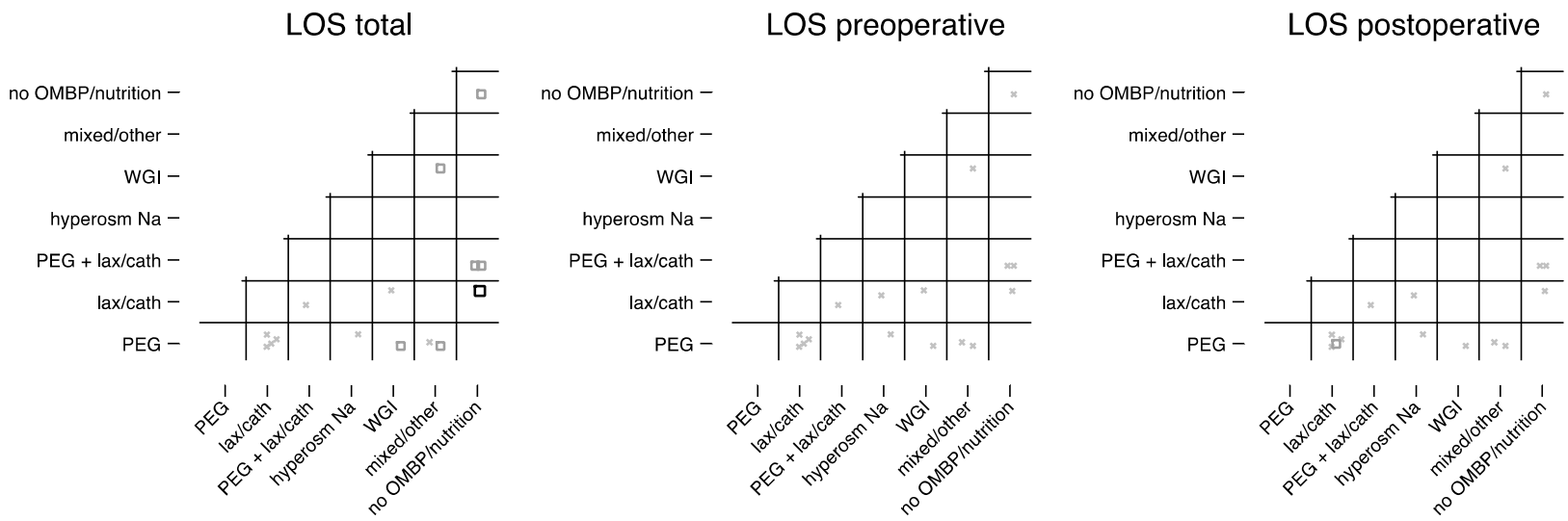
Note: Comparisons of alternative active OMBP strategies. Please consult the main text of the report for details on how this graph should be interpreted.

Figure 13. Summary of findings from studies comparing alternative active OMBP strategies (continued)



Note: Comparisons of alternative active OMBP strategies. Please consult the main text of the report for details on how this graph should be interpreted. The panel for extra-abdominal infections depicts more than one datapoint per study.

Figure 13. Summary of findings from studies comparing alternative active OMBP strategies (continued)



Note: Comparisons of alternative active OMBP strategies. Please consult the main text of the report for details on how this graph should be interpreted.

Assessment of Risk of Bias for RCTs Comparing Alternative Active OMBP Strategies

Studies did not allow detailed assessment of the risk of bias for several important aspects of study design. For example, information on the randomized sequence generation and allocation concealment was deemed unclear in 14 and 19 of the 23 RCTs, respectively. Similarly, blinding of patients, physicians, and outcome assessors were deemed unclear in 19, 16, and 12 of the RCTs. In contrast, information on withdrawals and dropouts was generally well reported. Of the studies reporting relevant information, only three reported a dropout rate of more than 10% (two in both arms; one only in a single arm) and only one study had evidence of differential dropout (defined as a more than 10% difference in the dropout rate between arms). As shown in Figure 14, only few studies provided information on each of the outcomes of interest, raising some concerns about selective outcome reporting. Overall, based on the number of items considered indicative of low risk, ten studies were considered to be at high risk of bias, 12 to be at intermediate risk of bias, and 1 to be at low risk of bias. As always, aggregated risk of bias assessments need to be interpreted with caution, given our inability to fully distinguish inappropriate study design from poor reporting and lack of context-specific evidence that the risk items we assessed are indeed associated with bias.

RCTs of Alternative Active OMBP Strategies in Children

Two studies, both conducted in India, compared alternative active OMBP strategies in children undergoing colorectal surgery (a minority of children underwent procedures for indications other than colorectal surgery in both studies). Both studies were considered to be at high risk of bias and provided limited information on the generation of the randomized sequence and allocation concealment.

The first study[41] enrolled 54 children and compared whole gut irrigation with normal saline with added potassium (26 patients) versus PEG (28 patients). Four patients developed a wound infection in the whole-gut irrigation group and three in the PEG group; the difference was not statistically significant (P = 0.699).

The second study [79]enrolled 126 children and compared whole gut irrigation with a NaCl solution (40 patients), PEG (55 patients), and Ringer's lactate (31 patients). Wound infections developed in two, three, and two patients in the NaCl, PEG, and Ringer's lactate treatment groups, respectively; the difference between groups was not statistically significant (P > 0.99).

NRCSs Comparing Active OMBP Strategies

Only two NRCSs reported information on the comparison of alternative active OMBP strategies. The first study[56] was a secondary analysis of a previously completed multicenter RCT of alternative antibiotic treatments (comparing ertapenem versus cefotetan) for patients undergoing elective colorectal surgery. Inclusion in the parent trial required patients to have undergone bowel preparation with PEG or sodium phosphate. Patients were followed up for SSI development for a period of 4 weeks. Of a total of 670 evaluable patients, 303 had OMBP with PEG and 367 with sodium phosphate. The overall rate of SSI was lower among patients who received sodium phosphate as compared with those who received PEG, however the difference was not statistically significant in multivariable analysis (OR = 0.69, 95% CI 0.46 to 1.02; P = 0.07). The study also reported a subgroup analysis by resection subtype, comparing PEG versus

sodium phosphate among patients who underwent resection of the rectum versus those who underwent other colorectal surgical procedures. The magnitude and direction of effects was similar in both groups [using data in the paper, we calculated the unadjusted OR to be 0.59 (95% CI 0.42 to 0.83) and 0.67 (95% CI 0.46 to 0.99), for patients undergoing and not undergoing rectal resection, respectively]. The test for interaction between resection type and preparation regimen was not statistically significant (P = 0.64). The study was considered to be at intermediate risk of bias, mainly due to concerns about confounding bias (some of the reported analyses were unadjusted).

The second study[32] was a retrospective cohort comparing three groups: mannitol with ceftriaxone (150 patients), mannitol with ceftriaxone plus metronidazole (160 patients), and traditional preparation with purgatives and enemas, combined with neomycin and metronidazole (140 patients). Of note, 110 of the 140 patients in the traditional preparation group were not treated concurrently with the patients receiving mannitol (i.e., they were historical controls). A comparison across all three groups found statistically significant differences for the outcomes of peritonitis requiring reoperation and a composite outcome of all infectious complications (P = 0.008 and P < 0.001, respectively). Differences were not statistically significant for other outcomes assessed, including wound infection, intra-abdominal abscess necessitating reoperation, anastomotic insufficiency, death due to peritonitis, or all cause mortality. For all outcomes, event rates were higher in the traditional preparation group and lower in the two mannitol study groups. The study was considered to be at high risk of bias, on the basis of concerns regarding confounding bias (all comparisons between groups were unadjusted and patients in the traditional preparation group were not treated concurrently with those in the mannitol groups).

Comparisons of Inpatient Versus Outpatient OMBP

One RCT and one NRCS compared inpatient versus outpatient use of OMBP. The RCT[51] compared inpatient versus outpatient preparation using of PEG in 100 patients undergoing elective colorectal surgery (51 inpatient versus 49 outpatient). Overall, the study was considered to be at high risk of bias and provided limited information regarding blinding and allocation concealment. Two patients in each group developed a wound infection; the difference between groups was not statistically significant (P > 0.99). Information was not provided regarding the treatment received by patients experiencing two additional outcome events (1 intra-abdominal abscess and 1 enterocutaneous fistula). However, the difference between the two groups for these outcomes was also nonsignificant (P > 0.99).

The NRCS[64] retrospectively compared inpatient versus outpatient use of PEG in 319 patients who underwent colectomy with primary anastomosis (174 inpatient vs. 145 outpatient). The study was considered to be at high risk of bias because of concerns regarding confounding bias (all comparisons were unadjusted). One death was observed in each study group (P > 0.99). Three patients who received inpatient OMBP and where discharged to a rehabilitation facility, no patients in the outpatient group required care in such a facility (P = 0.25). Length of hospitalization was 10.7[i] days in the inpatient group and 9 days in the outpatient group and the difference was not statistically significant (which the authors reported to be statistically nonsignificant).

[i]The number was reported as 107 (rather than 10.7), but based on the statistical analysis results reported in the study and the range of values (6-41 days) 10.7 appears to be the most likely correct value.

Key Question 2. How does the use of OMBP, with or without cointerventions (e.g., antibiotics, rectal enema), compare with no OMBP or with OMBP plus different cointerventions with respect to presurgical and postsurgical adverse events?

a. What are the comparative adverse events of the various OMBP strategies?

In this section we summarize the evidence on the following predefined potential adverse events of OMBP: nausea, vomiting, dehydration, electrolyte imbalance, kidney damage, emergency admissions prior to surgery, cancelled, delayed, or rescheduled surgeries, allergic reactions, and seizures. Based on preliminary literature searches and discussions with TEP members, we expected that evidence on these outcomes would be sparse in comparative studies (both randomized and nonrandomized). We therefore also considered evidence from noncomparative (single group) cohort studies where all patients received OMBP.

The organization of the subsequent sections follows that of Key Question 1: we first discuss comparative studies of OMBP versus enema or no preparation, followed by comparative and noncomparative (single group) studies of alternative active OMBP strategies. The risk of bias assessment of comparative studies has already been presented in the section pertaining to Key Question 1. Thus, in the risk of bias subsection we provide assessments only for single-group cohorts.

Comparisons of OMBP Versus No OMBP

RCTs Comparing OMBP Versus No Preparation

Of the 18 RCTs included in main analyses comparing OMBP with or without enema versus enema alone or no preparation, only two provided information pertaining to the prespecified adverse events (one for nausea and one for renal failure).

Nausea

In one study[35] patients were asked to rate their degree of nausea using a 1-to-5 ordinal scale (higher values indicated more severe symptoms). Of 233 randomized patients, 185 (95 OMBP-treated and 90 controls) replied to the questionnaire. The frequency of nonresponse to the questionnaire was not significantly different among OMBP-treated and untreated patients (P = 0.40). Nausea (the cut off on the scale was not reported) was reported by nine OMBP-treated patients and eight controls (P = 0.77).

Renal Failure

One study[36] comparing OMBP versus no preparation reported that three of 89 patients receiving OMBP versus one of 89 patients receiving no preparation experienced acute renal failure (P = 0.62).

Comparisons of OMBP Versus No OMBP in NRCSs

None of the seven NRCSs comparing OMBP versus no preparation reported information on the prespecified adverse events.

Comparisons of Alternative Active OMBP Strategies

RCTs Comparing Alternative OMBP Strategies in Adults

As discussed in the corresponding section of Key Question 1, studies of alternative active OMBP strategies used very diverse OMBP strategies, assessed heterogeneous outcomes, and, raised concerns of selective outcome reporting (and other risk of bias dimensions). Regarding the assessment of adverse events, studies utilized a diverse set of symptom scales to measure severity of patient reported adverse events (nausea, vomiting, fatigue, bloating, cramping, etc.). In most studies adverse event definitions were not clearly described, making it impossible to consistently compare outcomes across studies. Only a single study[70] provided a copy of the questionnaire that was administered to patients; no study described whether the validity of the questionnaires had been formally assessed.

For these reasons, we have used the same approach as in Key Question 1 and summarize findings using scatterplots that map the comparisons reported and the direction and statistical significance of effects (Figures 14 and 15). The underlying data, together with additional extracted information are accessible online (at http://srdr.ahrq.gov/).

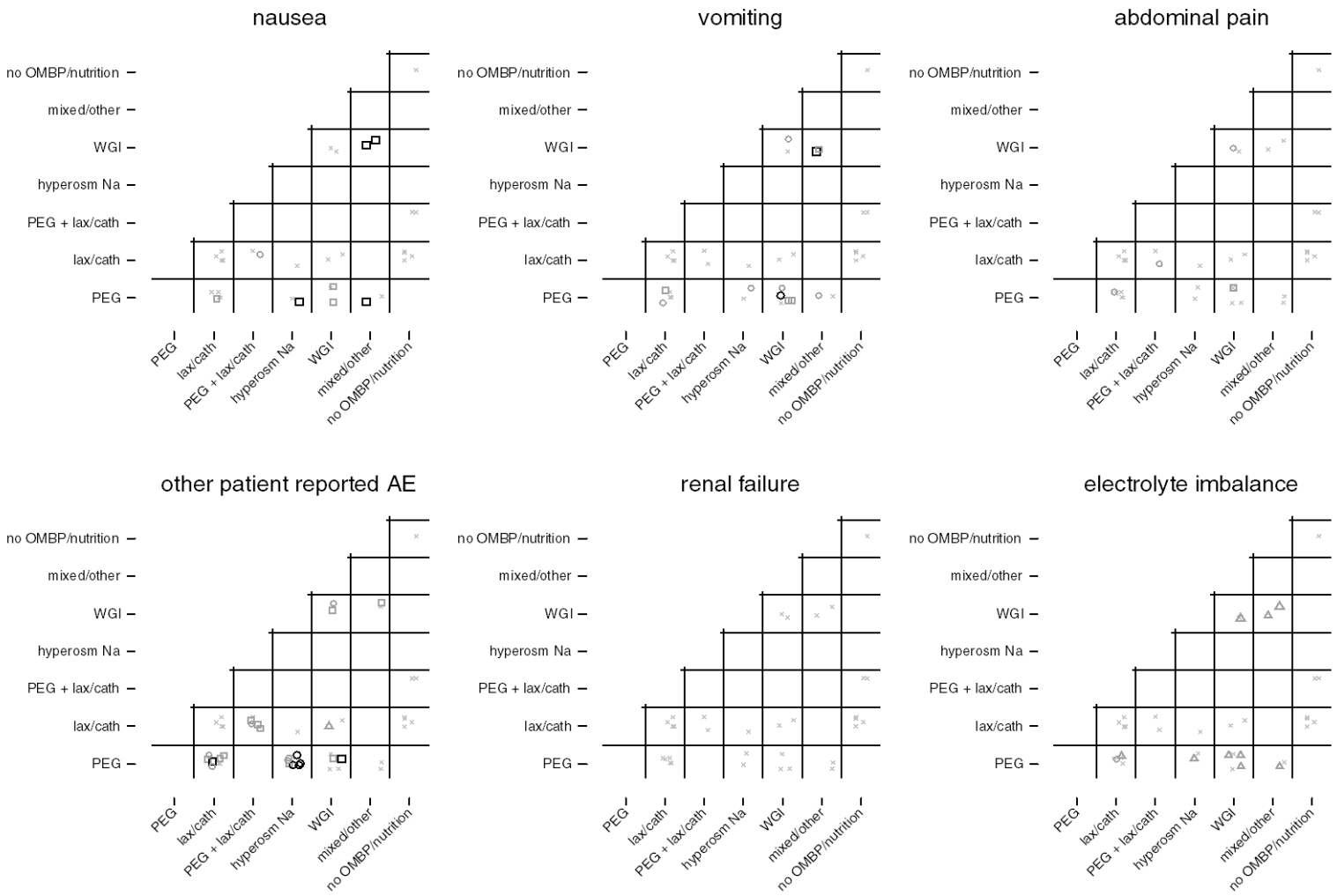
Based on Figures 14 and 15 we make the following observations, which are in accordance with the corresponding descriptions in Key Question 1:

Only 13 out of the 28 cells (comparisons) have some empirical information (13 for binary outcomes; 10 for continuous outcomes), i.e., have at least one study (one marker) provided evidence about them. We have been quite lenient in categorizing the individual active OMBP comparisons into the seven conceptual categories represented by rows and columns in each panel; were we to use a more granular categorization, the matrix would be larger, and there would be fewer studies in each of the cell.

Outcomes are assessed or reported in sufficient detail in a minority of the conducted studies. Most reported data fall into the outcome category other patient-reported adverse events (Figure 14, first page, lower left panel), which is indicative of the nonstandardized reporting. Where two or more studies provided information for the same outcome no conclusions could be reached regarding the comparative effectiveness of interventions. Renal failure, an outcome considered important given that many OMBP strategies involve ingestion of large volumes of solutions, was not reported in any study. This nonstandardized and partial reporting of harms represents a lost opportunity, i.e., could have been averted by better planning of the conduct and reporting of said studies.

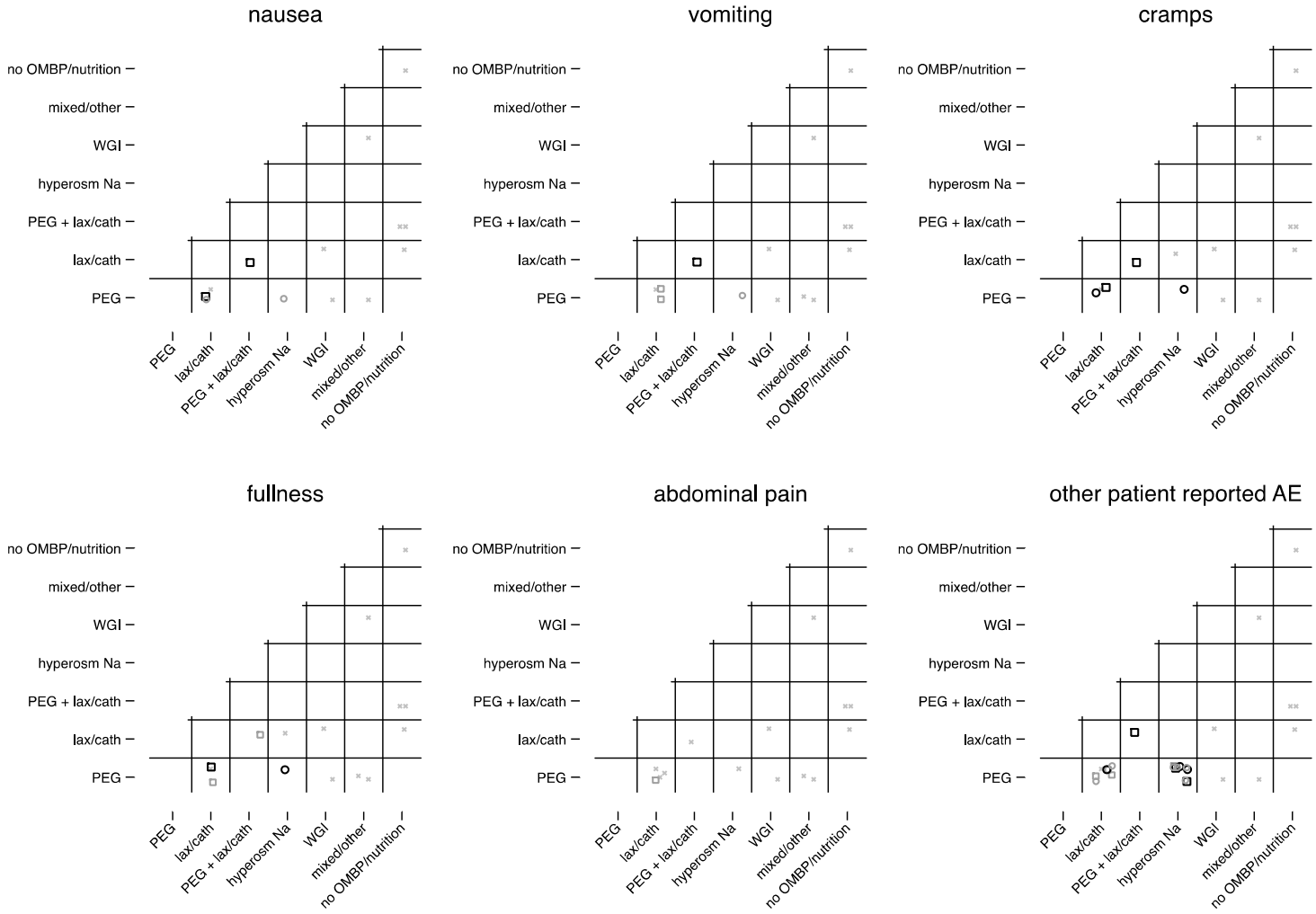
Finally, **the majority of the available studies are small, and probably underpowered to detect modest or small effect sizes, let alone relatively rare harms**. Across all 88 analyzable results (outcome/comparison combinations) 27 were statistically significant —visually, in the three Figures the gray hollow markers outnumber the black ones. However, there is no readily discernible pattern. Because the true distribution of effects in this body of literature is unknown, and because these analyses are not independent (per study, they are in the same patients), one cannot make statements on whether the identified statistically significant findings are more than what would be expected by chance.

Figure 14. Summary of findings from studies comparing alternative active OMBP strategies (results reported as binary outcomes)



Note: Comparisons of alternative active OMBP strategies. Please consult the main text of the report for details on how this graph should be interpreted.

Figure 15. Summary of findings from studies comparing alternative active OMBP strategies (results reported as continuous outcomes)



Note: Comparisons of alternative active OMBP strategies. Please consult the main text of the report for details on how this graph should be interpreted.

RCTs of Alternative Active OMBP Strategies in Children

Two studies reported information on the comparison of alternative OMBP strategies in children. The studies only reported information on vomiting and electrolyte imbalance.

Vomiting

Both studies reported information on vomiting. In the first study[41] 7 of 28 patients treated with whole gut irrigation with PEG experienced vomiting, compared to 13 of 23 patients treated with whole gut irrigation with normal saline and added potassium (P = 0.09). The second study[79] compared whole gut irrigation with PEG, Ringer's lactate and NaCl and reported that vomiting was experienced by 11 of 55 patients, 5 of 31 patients, and 2 of 40 patients, respectively (P = 0.10, across groups).

Electrolyte Imbalance

One study[79] reported that no clinically significant electrolyte imbalances were observed after OMBP in the three compared groups (whole gut irrigation with PEG, NaCl, or Ringer's lactate).

NRCSs Comparing Alternative Active OMBP Strategies

None of the two NRCSs comparing alternative active OMBP strategies versus no preparation reported information on the prespecified adverse events.

Single-Group Cohorts of Active OMBP Strategies

Six studies met our inclusion criteria for single group cohorts and reported results on at least one of the prespecified adverse events of pertaining to Key Question 2. Of note all six studies were large comparative studies of antibiotic treatments (5 studies) or enema use (1 study) for patients with colorectal cancer. Because these studies used a uniform OMBP treatment for all patients – for the purposes of this report – they were treated as single group studies.

Vomiting

In one study[47] of OMBP with saline or mannitol the rate of vomiting was approximately 1.6 percent (5 of 308 patients). All patients were also receiving metronidazole and ceftriaxone. Vomiting was not attributed to the OMBP drugs by the authors. No vomiting was reported among 307 patients included in the same study and treated with the same OMBP regimen, plus metronidazole and cefepime instead of ceftriaxone.

In one study[84] of OMBP with senna the rate of vomiting was approximately 3.9 percent (20 of 517 patients; 277 received povidone-iodine and 240 sodium hypochlorite enema). Vomiting was not attributed to the OMBP drugs by the authors.

Finally, in one study[48] of OMBP with sodium phosphate the rate of vomiting was approximately 17 percent (51 of 300 patients; 100 received three doses of oral antibiotic, 100 received a single dose, and 100 received no oral antibiotics). Vomiting was not attributed to the OMBP drugs by the authors; the rate of vomiting was 31 percent among patients receiving three doses of oral antibiotics, 11 percent among those receiving a single dose, and 9 percent among those receiving no oral antibiotics (P < 0.001 for the comparison across groups).

Nausea

One study[47] of OMBP with saline or mannitol plus metronidazole and ceftriaxone reported nausea in approximately 1 percent of patients (3 of 308). Nausea was not attributed to the OMBP drugs by the authors. No nausea was reported among 307 patients included in the same study and treated with the same OMBP regimen plus metronidazole and cefepime (instead of ceftriaxone).

In one study[48] of OMBP with sodium phosphate the rate of nausea was approximately 25 percent (75 of 300 patients; 100 received three doses of oral antibiotic, 100 received a single dose, and 100 received no oral antibiotics). The authors did not attribute nausea to the OMBP drugs. The rate of nausea was 44 percent among patients receiving three doses of oral antibiotics, 18 percent among those receiving a single dose, and 13 percent among those receiving no oral antibiotics ($P < 0.001$ for the comparison across groups).

Vomiting and Nausea (Combined)

In one study[61] of OMBP with PEG, the rate of nausea and vomiting was approximately 2.2 percent (11 of 491 patients; 245 received intravenous antibiotics and 246 received both intravenous and oral antibiotics). The authors did not attribute these events to the OMBP drugs (they considered them probably related to the antibiotics).

Allergic Reactions

In one study[47] of OMBP with enemas and laxatives the rate of allergic reactions (maculopapular rash) was 2.7 percent (7 events among 263 patients). However, all patients were also receiving cephalosporin antibiotics. The authors did not attribute the allergic reactions to the OMBP drugs.

In a study[91] of OMBP with saline or mannitol the rate of allergic reactions was approximately 1 percent (3 of 308 patients). All patients were also receiving ceftriaxone plus metronidazole antibiotics. The authors did not attribute the allergic reactions to the OMBP drugs.

In a third study[61] of OMBP with PEG, no hypersensitivity reactions were observed (0 of 491 patients; 245 received intravenous antibiotics and 246 received both intravenous and oral antibiotics).

In a fourth study[45] of OMBP with sodium phosphate and enemas the rate of urticaria was less than 1 percent (1 of 241 patients; 121 treated with cefoxitin and 120 treated without parenteral antibiotics). The authors did not attribute the allergic reaction to the OMBP drugs (urticaria developed in a patient in the cefoxitin group).

Risk of Bias in Single Group Cohort Studies

(Please refer to the corresponding section of Key Question 1 for a description of the risk of bias of the comparative studies.)

We assessed the risk of bias of these studies using a set of items based on the Newcastle-Ottawa scale. Briefly, we examined whether there was risk of selection bias, the methods of exposure ascertainment, whether patients were outcome-free at baseline, whether rates of events were adjusted for key patient characteristics (e.g., whether incidence rates were standardized or stratified by age or sex), the methods for outcome assessment, and the adequacy of followup.

These studies were prospective (and were designed to provide information on the use of antibiotics or enemas). There was low risk that patients had the adverse events at baseline. Exposure was protocol-determined in all cases. Four of six studies explicitly reported enrolling consecutive patients, thus reducing the risk of selection bias. However, no study reported

adjustment or standardization of event rates by key patient characteristics. Methods for outcome ascertainment were unclear in six studies, performed by an independent observer in one study, and based on a combination of self-report and care provider observation in two cases.

Comparisons of Inpatient Versus Outpatient OMBP

The two studies (1 RCT[51] and 1 NRCS[64]) comparing inpatient versus outpatient administration of OMBP did not report information on the prespecified adverse events of interest.

Key Question 2. How does the use of OMBP, with or without cointerventions (e.g., antibiotics, rectal enema), compare with no OMBP or with OMBP plus different cointerventions with respect to presurgical and postsurgical adverse events?

b. What are the comparative adverse events of OMBP in subgroups of patients especially susceptible to the potential adverse events?

We sought information on adverse events of OMBP when used by patients who may be particularly susceptible to adverse events. Specifically, we aimed to identify evidence on the impact of OMBP on adults and children with cardiovascular or pulmonary disease, patients at the extremes of age, patients who have undergone adjuvant chemotherapy or radiotherapy, and patients with diabetes, kidney disease, or compromised immune function (including drug-induced immunosuppression) who undergo elective colorectal surgery.

No study in this report provided such information. Studies often excluded individuals who would be at particular high risk of adverse events following the use of OMBP. For example, several studies reported excluding patients with severe renal failure or hypertension at diagnosis. Among studies that did not report such exclusions (including a minority that explicitly stated including individuals belonging to the susceptible groups of interest to this Key Question), none reported outcome information limited to the populations of interest. Because of the sparseness of the evidence on these subgroups of patients, we considered the strength of the evidence to be insufficient.

Discussion

Key Findings

We reviewed 60 studies spanning 40 years of empirical data on the benefits and harms of alternative OMBP strategies for elective colorectal surgery. After examining the literature for a wide range of clinical outcomes, we found no evidence that OMBP with or without enema differs from enema or no preparation. However, the uncertainty accompanying the estimated treatment effects was considerable. Based on the boundaries of the credible intervals, one cannot exclude a modest (e.g., 30 to 50 percent) change in odds in either direction for all-cause mortality, anastomotic leakage, wound infection, and peritonitis. This uncertainty is explained by the relatively small sample size of included studies and the relative rarity of key clinical events such as death, anastomotic leakage, reoperation, and severe infection. Of more concern is that important subgroups, such as anatomic location (colon vs. rectum) and type of surgery (laparoscopic versus open) were sparsely reported in the published literature, as was information on important potential effect modifiers (e.g., oral or parenteral antibiotics).

We also found that the evidence on the comparative effectiveness and safety of alternative preparation strategies was insufficient and probably not very applicable to current clinical practice. Information on the safety of OMBP was not consistently reported. It is also unclear whether the type or frequency of adverse events of OMBP differ across patient subgroups, e.g., in patients with cardiac, pulmonary, or renal disease; cancer; suppressed immune function; or patients receiving chemotherapy, radiotherapy or immunosuppression.

We observed that the early trials explored comparisons among alternative active OMBP strategies, with later published and recent studies evaluating the more fundamental question of using versus not using OMBP. This reflects an apparent shift in the prevailing opinions about the role of OMBP prior to elective colorectal surgery. Since the early 1970's OMBP was widely considered highly desirable, presumably on the basis of pathophysiological and practical rationales but without serious concomitant empirical support.[4,13] Clinical equipoise presumably existed between alternative OMBP strategies; today, it is probably fair to state that the question is between using simple short-duration OMBP regimens versus not.

Assessment of the Strength of Evidence

Table 7 presents a summary of the report's key findings for each Key Question. Strength of evidence was assessed separately for the comparison of OMBP (with or without enema) versus no preparation and the comparison of OMBP versus enema, for consistency with previous work on the same topic and because studies of OMBP versus enema generally exhibited greater statistical heterogeneity, as compared to studies of OMBP versus no preparation. Our conclusions for the overall comparison of OMBP versus no OMBP are similar. Please see the Methods section for a detailed discussion of our approach to rating the strength of evidence. Overall, we found weak evidence that OMBP and no preparation had similar effectiveness with respect to the outcomes of all-cause mortality, anastomotic leakage, wound infection, and peritonitis. The ORs for these outcomes were all close to 1 and the credible intervals from pairwise meta-analyses excluded large differences (e.g., increasing the odds of an outcome by 2-3 times). For all other outcomes for this comparison, results were too imprecise to exclude even larger treatment effects and thus insufficient to draw conclusions. Similarly, we found that evidence on the comparison of OMBP versus enema was insufficient for all outcomes of interest.

Table 7. Summary assessment of the strength of evidence

Population	Outcome	Comparison	Assessment of the Strength of Evidence	Key Findings and Comments*
KQ1: Adult patients undergoing colorectal surgery	All-cause mortality	OMBP versus no prep	Low (for lack of difference)	The OR in meta-analysis of 10 studies was 1.09 (95% CrI 0.57 to 2.99), indicating moderate to substantial uncertainty in the summary estimate. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
		OMBP versus enema	Insufficient	The OR in meta-analysis of 4 studies was 1.99 (95% CrI 0.27 to 18.45), indicating substantial uncertainty in the summary estimate. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
	Anastomotic leakage	OMBP versus no prep	Low (for lack of difference)	The OR in meta-analysis of 12 studies was 1.06 (95% CrI 0.73 to 1.73), indicating moderate uncertainty in the summary estimate. Pairwise analysis concurred. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
		OMBP versus enema	Insufficient	The OR in meta-analysis of 4 studies was 1.24 (95% CrI 0.38 to 4.72), indicating substantial uncertainty in the summary estimate. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.

Table 7. Summary assessment of the strength of evidence (continued)

Population	Outcome	Comparison	Assessment of the Strength of Evidence	Key Findings and Comments*
KQ1: Adult patients undergoing colorectal surgery (continued)	Wound infection	OMBP versus no prep	Low (for lack of difference)	The OR in meta-analysis of 12 studies was 1.27 (95% CrI 0.95 to 1.88), indicating moderate uncertainty in the summary estimate. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
		OMBP versus enema	Insufficient	The OR in meta-analysis of 4 studies was 1.04 (95% CrI 0.37 to 3.34), indicating substantial uncertainty in the summary estimate. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
	Peritonitis/ intra-abdominal infection	OMBP versus no prep	Low (for lack of difference)	The OR in meta-analysis of 10 studies was 0.84 (95% CrI 0.45 to 2.00), indicating moderate uncertainty in the summary estimate. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
		OMBP versus enema	Insufficient	The OR in meta-analysis of 4 studies was 0.99 (95% CrI 0.21 to 4.68), indicating substantial uncertainty in the summary estimate. Studies were at moderate ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.

Table 7. Summary assessment of the strength of evidence (continued)

Population	Outcome	Comparison	Assessment of the Strength of Evidence	Key Findings and Comments*
KQ1: Adult patients undergoing colorectal surgery (continued)	Reoperation	OMBP versus no prep	Insufficient	The OR in meta-analysis of 6 studies was 1.15 (95% CrI 0.73 to 2.50), indicating substantial uncertainty in the summary estimate. Studies were at moderate ROB. There was some concern regarding selective outcome reporting. There was statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected; the 2.5th percentile of the posterior distribution of the between-study variance of the log-OR was 0.27.
		OMBP versus enema	Insufficient	The OR in meta-analysis of 2 studies was 0.50 (95% CrI 0.03 to 6.12), indicating substantial uncertainty in the summary estimate. Studies were at moderate ROB. There was some concern regarding selective outcome reporting . There was statistical evidence of inconsistency; however, estimates were imprecise.
	All other effectiveness outcomes	OMBP versus no prep	Insufficient	Few if any studies reported information; study-specific results were imprecise. There was concern about selective outcome reporting.
		OMBP versus enema	Insufficient	Few if any studies reported information; study-specific results were imprecise. There was concern about selective outcome reporting.
	All outcomes	Alternative active OMBP strategies versus each other	Insufficient	Individual studies compared diverse interventions and reported outcomes heterogeneously, precluding synthesis. Study specific results were imprecise. Studies were at moderate to high ROB. There was no indication of selective outcome reporting. There was no statistical evidence of inconsistency; however, because there are only a few studies and most of them are small, statistical heterogeneity cannot be reliably detected.
		Inpatient vs. outpatient OMBP	Insufficient	Only 2 studies were available (1 RCT, at moderate ROB, and 1 NRCS, at high ROB). Study-specific estimates were imprecise.
KQ1: Children undergoing elective colorectal surgery	All outcomes	All comparisons	Insufficient	Only 2 studies provided evidence on children undergoing elective colorectal surgery. Studies reported information only for wound infection (no other effectiveness outcomes were assessed) and produced imprecise results.

Table 7. Summary assessment of the strength of evidence (continued)

Population	Outcome	Comparison	Assessment of the Strength of Evidence	Key Findings and Comments*
KQ1: Patients undergoing elective surgery for right-sided or left-sided colon, or rectal surgery	All outcomes	All comparisons	Insufficient	Only a minority of studies provided anatomic location specific results (and only for anastomotic leakage). Subgroup analyses did not reveal a difference in the effect of OMBP compared to enema or no preparation between colon and rectal surgery population with respect to the outcome of anastomotic leakage. Results were very imprecise for both subgroups and anatomic location was heterogeneously defined across studies. There is concern regarding selective analysis reporting.
KQ2: Patients undergoing elective colorectal surgery (general surgical population)	Adverse events	All comparisons	Insufficient	When interpreting the data available for this review results are insufficient. Most prespecified adverse events of interest were evaluated by a small minority of studies or not examined at all. When reported, study-specific results did not lead to definitive conclusions due to imprecise results, and lack of validation of the measurement scales used (for patient symptom scores). However, the evolution of the preparation strategies used in trials (with most recent studies using PEG-based strategies, possibly in combination with laxatives) indicates that these preparations may be considered the safest or more palatable for patients.
KQ2: Patients undergoing elective surgery who may be at particular risk for adverse events	Adverse events	All comparisons	Insufficient	No relevant studies were identified.

CrI = credible interval; KQ = key question; NRCS = nonrandomized comparative study; no prep = no OMBP and no enema; OR = odds ratio; PEG = polyethylene glycol; RCT = randomized controlled trial; ROB = risk of bias

*Summary estimates reported in this table are those from the pairwise Bayesian meta-analysis. Results from extensive sensitivity analyses and network meta-analyses were consistent with those presented in the Table.

Compared to a recent Cochrane Review of OMBP we have included a broader spectrum of study designs (including NRCSs and single group cohorts) and have performed more extensive data analyses using state-of-the art methods that more fully account for the uncertainties in the synthesis of evidence.[97] Thus, our interpretation of the evidence base is more conservative than that of the Cochrane review on the same topic[1] and other recent meta-analyses.[98-101] While, similarly to those reviews, we did not find evidence of clear benefit from OMBP, the wider credible intervals around our results lead us to conclude that modest benefit or harm cannot be excluded. Given the very large number of colorectal surgeries performed annually, modest effects can be clinically significant and therefore further research is urgently needed to provide a definitive answer. In the future research section we argue that a comprehensive evaluation of the comparative effectiveness of OMBP is entirely possible.

Applicability

The existing evidence base comparing OMBP (with or without enema) versus enema or no preparation, appears to be applicable to U.S. settings. Studies enrolled patients with an age distribution similar to that of patients undergoing colorectal surgery in the U.S., and for indications that represent the most prevalent indications in U.S. clinical practice. However, none of these studies has been conducted in the U.S., raising some concern that system-level differences may render findings less applicable to surgical practice. Findings may be most applicable to patients undergoing colon surgery; data on patients undergoing rectal surgery were sparse, and thus the applicability of findings to this population is at best unclear. Similarly, the applicability of our findings to patients undergoing laparoscopic colorectal surgery is unclear, because few studies reported relevant information.

Preparation of the bowel is only one of many supportive interventions used prior to colorectal surgery with the goal of attaining better surgical outcomes and earlier postoperative recovery. Other pertinent interventions include preoperative (counseling, feeding, etc.), perioperative (avoiding hypothermia, using epidural analgesia, etc.), and postoperative (e.g., avoiding nasogastric tubes and drains, encouraging early mobilization and oral feeding) aspects of care.[102] Often such interventions are "bundled" in "Early Recovery After Surgery" (ERAS) programs that aim to reduce the length of stay and improve clinical outcomes. Although existing trials of ERAS programs include, among other things, the omission of OMBP as an intervention component, it is not clear how our findings apply in settings where additional ERAS components are implemented.[102]

Regarding studies comparing alternative active OMBP strategies, applicability appears to be limited, because they examined OMBP regimens that have fallen out of use in modern practice. Overall, the reviewed studies of active versus active OMBP strategies provide little information on comparative effectiveness and safety that is applicable to current clinical use. Further, there is reemerging interest in the use of oral antibiotics agents in bowel preparation. The majority of the included studies did not use oral antibiotics, but we deemed that this did not limit their applicability.

Limitations of the Evidence

On the basis of the reviewed studies, we believe that the evidence regarding OMBP for colorectal surgery is limited in the following ways:

- Most *studies enrolled small numbers of patients and reported low event rates for major clinical events* during followup. This led to imprecise study-specific results; for many

outcomes substantial imprecision remained after combining evidence from most available published trials.

- Studies *did not report results for important clinical subgroups,* particularly those defined by anatomic location of surgery (colon versus rectal surgery) and the type of surgical procedure performed (e.g., open versus laparoscopic surgery).
- *Studies did not consistently report information on potential effect modifiers* (particularly the co-administration of oral antibiotics).
- The *literature comparing alternative active OMBP strategies for colorectal strategy was fragmented* because studies used a large number of diverse preparation regimens and reported results for heterogeneous, often poorly defined, outcomes. It is not clear how most of these map to current standard definitions of outcomes (e.g., CDC definitions for wound infections).
- *Nonrandomized trials, and particularly observational studies, could not effectively supplement the results of randomized trials* because exposure ascertainment was often not done in detail, analyses were not adjusted for or stratified by important patient-, disease-, or system-level characteristics, and methods to adequately control confounding bias were not consistently used.
- Studies, particularly those conducted in earlier years, typically did not report adequate information to *judge whether the outcome definitions of reported events matched currently recommended definitions* (e.g., those proposed by the Center's for Disease Control and Prevention).

Limitations of This Review

Several limitations need to be considered when interpreting our results. First, our conclusions, to a large extent, reflect weaknesses of the underlying evidence base. For example, our ability to perform subgroup analyses to explore the impact of patient-, disease-, or system-level characteristics on the effectiveness of OMBP is limited by the incomplete reporting of relevant information in the published papers. Second, we excluded studies not published in English. Previous work that included non-English language studies identified only three publications with small sample sizes (totaling 269 patients). Third, we have relied mainly on electronic database searches and perusal of reference lists to identify relevant studies. Unpublished relevant studies may have been missed. Fourth, indexing of nonrandomized studies – and single-group cohort studies in particular – is less complete than that of randomized trials and we may have failed to identify relevant studies. However, we did not use search filters that limit results to specific study designs, in order to increase the sensitivity of our searches.

Ongoing Research

A search on May 15, 2013, in the ClinicalTrials.gov registry identified 11 potentially relevant records. After full text review, 5 records of studies that are be expected to provide information relevant to the Key Questions of this report were identified (3 studies are comparisons of OMBP versus enema or no preparation; one is a comparison of two OMBP strategies and 1 is a comparison of OMBP against a nutritional intervention). Appendix G summarizes information from these studies. None of these studies provided results in the ClinicalTrials.gov database at the time of this search.

Evidence Gaps

Table 8 summarizes the evidence gaps with regards to the two Key Questions of this systematic review.

Table 8. Evidence gaps

Key Question	Category	Evidence Gap
Comparative effectiveness of OMBP strategies	General	• There was substantial uncertainty regarding the effectiveness of OMBP versus enema or no preparation for patients undergoing colorectal surgery.
	Population	• Limited information was available for patients undergoing elective rectal surgery. • Very limited information is available for patients undergoing laparoscopic surgery.
	Interventions & Comparators	• The optimal preparation regimen for patients undergoing elective colorectal surgery remains unclear. • Potential interactions between OMBP regimens and cointerventions (e.g., enema, oral antibiotics) have not been explored adequately.
	Outcomes	• Studies did not always use consistent outcome definition or did not provide adequate details on outcome ascertainment to reliably assess whether outcomes were "similar enough" across studies. • Studies often heterogeneously and incompletely reported key clinical results, representing a "lost opportunity" for synthesis across studies.
Adverse events of OMBP strategies	General	• Limited information was available for key adverse events of interest. • Many adverse events have not been evaluated in trials comparing alternative active OMBP strategies.
	Outcomes	• Limited information for specified outcomes across all investigated study designs. • Nonrandomized studies did not offer.
Adverse events in susceptible groups	General	• No studies provided information on OMBP-related adverse events in patient groups that may be particularly susceptible (adults and children with cardiovascular or pulmonary disease, extremes of age, patients who have undergone adjuvant chemotherapy or radiotherapy, and patients with diabetes, kidney disease, or compromised immune function).

OMBP = oral mechanical bowel preparation

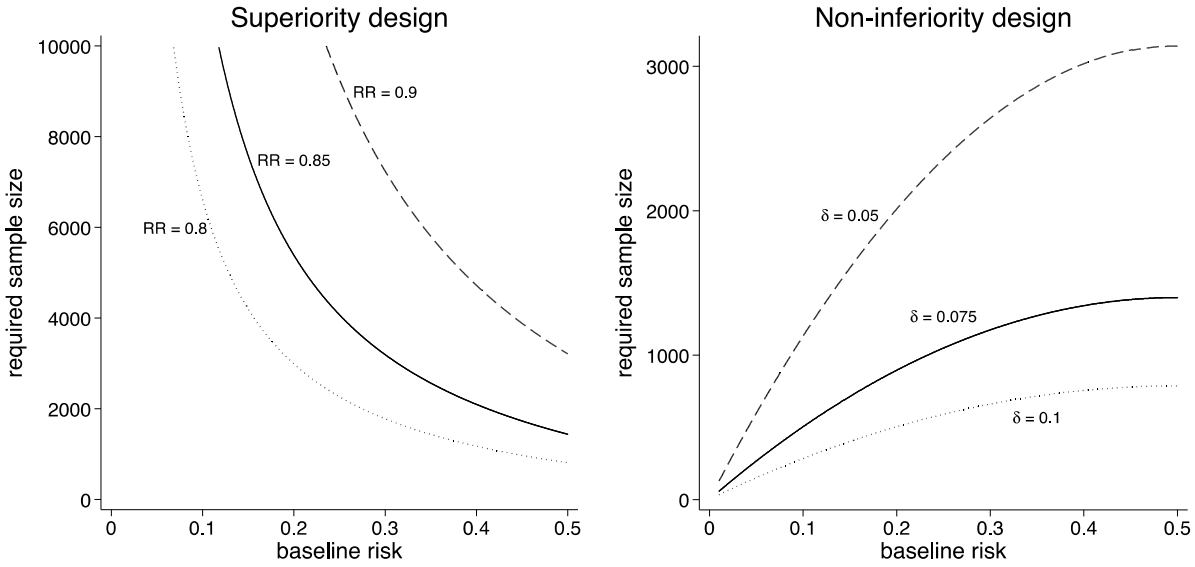
Future Research

This review identified major gaps in the published evidence on the comparative effectiveness and safety of OMBP for elective colorectal surgery. We believe that the following evidence gaps can be fruitful areas for future research:

- *RCTs to evaluate the comparative effectiveness of OMBP:* Given the uncertainty in meta-analytic estimates for most key clinical outcomes, a large, pragmatic RCT could substantially reduce uncertainty and definitively settle the main question. Conducting such a trial appears to be quite feasible, given the large number of elective colorectal surgeries performed annually, the relatively low cost of the interventions to be compared (OMBP, enema, no preparation), and that only a short-term followup (e.g., 30 days) is sufficient to assess almost all postsurgical outcomes of interest. Furthermore, if a non-inferiority design is adopted the required sample size should be relatively easy to accrue in a multicenter setting. Conducting a new large trial in the U.S. may facilitate uptake of the findings in this country by mitigating concerns about applicability. Consideration should also be given to factorial designs that can provide evidence on the comparative effectiveness of multiple interventions of interest (e.g., OMBP × enema × oral antibiotics). The study should be powered to evaluate major clinical outcomes including mortality, anastomotic leakage, and surgical site infections (using the latest CDC

guidelines[j]: superficial, deep incisional, organ/space). Figure 16 presents some example sample size calculations for different trial designs, treatment effects (or non-inferiority margins), and baseline event rates. Of note, a single primary study is unlikely to reliably address all decisionmaking uncertainties for all populations of interest in isolation from existing evidence; for this reason plans should be in place for a prospective meta-analysis to combine the results of a new study with previously completed trials (if possible using patient-level data).

Figure 16. Sample size requirements for superiority and noninferiority



The figure presents sample size calculations for 1:1 randomized trials comparing alternative OMBP strategies (e.g., OMBP vs. no preparation), over different baseline event rates (ranging from a low event rate of 1% to a common event rate of 50%, as could be observed for a composite outcome). The panel on the left presents sample size calculations for a superiority design, for alternative magnitudes of the treatment effect (RR; ranging from 0.9, a small protective effect to 0.8, a modest effect); calculations are based on a two-sided test for the difference of two proportions with α=0.05. The panel on the right presents sample size calculations for a non-inferiority design, for alternative non-inferiority margins (δ; ranging from a narrow marging of 5% to a somewhat broad margin of 10%); calculations are for a one-sided test for the difference of two proportions with α=0.025.

- *Conducting an individual patient data meta-analysis of existing trials of OMBP:* a consortium of investigators could perform such an analysis at much lower cost compared to a new trial. While it is unlikely that a reanalysis would result in more precise estimates, it would allow the opportunity to explore effects on subgroups for which no information is currently available (e.g., by anatomic location). By pooling existing datasets, an effort could be made to standardize outcome definitions and perform joint analyses for important subgroups of patients (e.g., colon versus rectal surgery). The results of such individual-patient data meta-analyses could be used to inform the design of future primary trials.
- *Conducting observational studies for the comparative effectiveness and harms of OMBP:* observational studies can inform the comparative effectiveness of alternative OMBP strategies, particularly for susceptible groups (e.g., patients with compromised function of

[j]Available at www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf; accessed May 30, 2013.

major systems) that have not been represented in the RCTs thus far. Such studies should have large sample sizes (to account for the low incidence of most outcome events) chosen on the basis of prospective power analyses, include patients representative of those seen in clinical practice, and use strong methods to address confounding bias (e.g., propensity score or instrumental variable methods). Further, exposure assessment should include the collection of details regarding the preparation strategy (i.e., the OMBP regimen and any cointerventions) and outcome ascertainment should be done using standardized definitions for all outcomes of interest. Quantitative bias analyses could be used to address concerns regarding unobserved confounding in nonrandomized studies. Although the use of observational data always requires additional assumptions for valid inference on treatment effects (compared to randomized designs), well designed observational studies can offer valuable information both regarding the effectiveness and adverse effects of OMBP.

Conclusions

We found weak evidence suggesting that OMBP has similar effectiveness with no preparation with respect to all-cause mortality, anastomotic leakage, wound infection, and peritonitis for patients undergoing elective colorectal surgery. However, the evidence base was too weak to confidently exclude either modest (30–50%) benefit or modest harm. Evidence on the comparative effectiveness of OMBP versus no preparation was insufficient for all other outcomes, as was evidence on the comparative effectiveness of OMBP versus enema for all outcomes. The body of literature on alternative active OMBP strategies was largely irrelevant to current surgical decisionmaking because the trials were underpowered, reported poorly defined outcomes, and compared preparations no longer in use. Future studies, including pooled reanalyses of existing data and new comparative studies (both randomized and nonrandomized), hold promise for informing clinical decisions.

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Appendix A. Search Strategy

The following search strategy was utilized in PubMed (September 6, 2013):

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(((surgic* OR surgery OR surgeri* OR operativ* OR operation OR
operations OR preoper* OR pre-oper* OR preoperative OR
"surgery"[Subheading] OR "surgical procedures, operative"[MeSH])

AND

("colorectal"[all fields] OR colon OR coloni* OR colore* OR recta* OR
rectu* OR "colo-rectal"  OR ((large) AND (bowel* OR intestin*)) OR
"Intestine, Large"[Mesh] OR colon[mesh] OR rectum[mesh])) OR
("Colorectal Surgery"[Mesh]))

AND

(prepara* OR enema* OR cathartics[MeSH] OR cathartic* OR polyethylene
glycols[MeSH] OR (polyethylene AND (glycol OR glycols)) OR
phosphates[MeSH] OR phosphate* OR "Laxatives"[MeSH] OR laxative* OR
"Senna Extract"[Mesh] OR (senna AND extract*)  OR "Bisacodyl"[Mesh] OR
"bisacodyl"[all fields] OR "Cascara"[Mesh] OR "cascara"[all fields] OR
"Enema"[Mesh] OR "PEG"[all fields] OR "miralax"[all fields] OR
"golytely"[all fields] OR "nulytely"[all fields] OR "halflytely"[all
fields] OR "fleet"[all fields] OR "dulcolax"[all fields] OR "pico
salax"[all fields] )
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The search strategy was translated for use in the Cochrane Central Register Of Controlled Trials, EMBASE, and CINAHL. Searches in these databases only included years 2010 to 2013 (because earlier years had been covered by the Cochrane Review by Guenaga et al.[1]).

Appendix B. List of Excluded Studies by Reason for Exclusion

Appendix Table B1. Reasons for study exclusion

Reason for Exclusion	Reference Number
Irrelevant	1-80
N<10	81-100
No Primary Data	101-222
Not Elective Colorectal Surgery	223-276
Not English Language	277-415 416-540
Conference Proceedings	541-583
Non-Randomized Controlled Studies with N<100	584-650
Single Group Study with N<200 or No Reporting Outcomes of Interest	651-836

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Appendix C. Sensitivity Analysis for Pairwise Contrasts Using Bayesian Methods (Sensitivity to Study Selection)

Appendix Table C1. Sensitivity analysis for pairwise meta-analysis (adding or removing particular studies)

Sensitivity analysis	Outcome	Comparison	N studies (N events / N patients, per group)	OR (95% CrI); P value	Between-study variance (95% CrI)
Include Scabini, 2012	All cause mortality	OMBP vs. no OMBP	15 (49 / 2670 vs. 46 / 2668)	1.24 (0.72, 2.68)	0.13 (0.00, 1.72)
		OMBP +/- enema vs. no prep	10 (38 / 2024 vs. 40 / 2014)	1.09 (0.57, 2.99)	0.17 (0.00, 2.61)
		OMBP +/- enema vs. enema	5 (11 / 646 vs. 6 / 654)	2.02 (0.44, 10.44)	0.50 (0.00, 3.61)
	Anastomotic leakage	OMBP vs. no OMBP	17 (133 / 2822 vs. 129 / 2804)	1.09 (0.80, 1.61)	0.07 (0.00, 0.62)
		OMBP +/- enema vs. no prep	12 (102 / 2176 vs. 103 / 2150)	1.06 (0.73, 1.73)	0.09 (0.00, 0.95)
		OMBP +/- enema vs. enema	5 (31 / 646 vs. 26 / 654)	1.28 (0.50, 3.62)	0.35 (0.00, 3.26)
	Wound infection	OMBP vs. no OMBP	17 (277 / 2732 vs. 245 / 2727)	1.22 (0.96, 1.66)	0.04 (0.00, 0.40)
		OMBP +/- enema vs. no prep	12 (218 / 2086 vs. 190 / 2073)	1.27 (0.95, 1.88)	0.05 (0.00, 0.50)
		OMBP +/- enema vs. enema	5 (59 / 646 vs. 55 / 654)	1.17 (0.51, 3.07)	0.41 (0.00, 3.14)
Exclude Hughes, 1972	All cause mortality	OMBP vs. no OMBP	13 (42 / 2504 vs. 42 / 2493)	1.15 (0.64, 2.92)	0.16 (0.00, 2.38)
		OMBP +/- enema vs. no prep	9 (35 / 1978 vs. 38 / 1963)	1.07 (0.52, 3.38)	0.20 (0.00, 3.02)
		OMBP +/- enema vs. enema	4 (7 / 526 vs. 4 / 530)	1.99 (0.27, 18.45)	0.82 (0.00, 3.76)
	Anastomotic leakage	OMBP vs. no OMBP	16 (126 / 2702 vs. 124 / 2680)	1.08 (0.79, 1.63)	0.08 (0.00, 0.72)
		OMBP +/- enema vs. no prep	12 (102 / 2176 vs. 103 / 2150)	1.06 (0.73, 1.73)	0.09 (0.00, 0.95)
		OMBP +/- enema vs. enema	4 (24 / 526 vs. 21 / 530)	1.24 (0.38, 4.72)	0.61 (0.00, 3.59)
	Wound infection	OMBP vs. no OMBP	15 (259 / 2566 vs. 229 / 2552)	1.22 (0.94, 1.73)	0.05 (0.00, 0.47)
		OMBP +/- enema vs. no prep	11 (211 / 2040 vs. 180 / 2022)	1.32 (0.97, 2.08)	0.05 (0.00, 0.59)
		OMBP +/- enema vs. enema	4 (48 / 526 vs. 49 / 530)	1.04 (0.37, 3.34)	0.52 (0.00, 3.46)
Exclude studies using selective enema strategies	All cause mortality	OMBP vs. no OMBP	12 (42 / 2285 vs. 41 / 2276)	1.22 (0.65, 3.27)	0.20 (0.00, 2.51)
		OMBP +/- enema vs. no prep	10 (38 / 2024 vs. 40 / 2014)	1.09 (0.57, 2.99)	0.17 (0.00, 2.61)
		OMBP +/- enema vs. enema	2 (4 / 261 vs. 1 / 262)	5.44 (0.22, 293.40)	0.99 (0.00, 3.80)

	Anastomotic leakage	OMBP vs. no OMBP	14 (114 / 2437 vs. 119 / 2412)	0.99 (0.71, 1.48)	0.07 (0.00, 0.68)
		OMBP +/- enema vs. no prep	12 (102 / 2176 vs. 103 / 2150)	1.06 (0.73, 1.73)	0.09 (0.00, 0.95)
		OMBP +/- enema vs. enema	2 (12 / 261 vs. 16 / 262)	0.69 (0.11, 3.77)	0.64 (0.00, 3.69)
	Wound infection	OMBP vs. no OMBP	14 (244 / 2347 vs. 225 / 2335)	1.14 (0.88, 1.59)	0.04 (0.00, 0.45)
		OMBP +/- enema vs. no prep	12 (218 / 2086 vs. 190 / 2073)	1.27 (0.95, 1.88)	0.05 (0.00, 0.50)
		OMBP +/- enema vs. enema	2 (26 / 261 vs. 35 / 262)	0.67 (0.13, 3.27)	0.53 (0.00, 3.64)
Exclude studies enrolling mixed populations of children and adults	All cause mortality	OMBP vs. no OMBP	13 (45 / 2478 vs. 44 / 2467)	1.17 (0.66, 2.69)	0.13 (0.00, 1.97)
		OMBP +/- enema vs. no prep	9 (38 / 1952 vs. 40 / 1937)	1.10 (0.58, 2.99)	0.16 (0.00, 2.57)
		OMBP +/- enema vs. enema	4 (7 / 526 vs. 4 / 530)	1.99 (0.27, 18.45)	0.82 (0.00, 3.76)
	Anastomotic leakage	OMBP vs. no OMBP	15 (119 / 2630 vs. 120 / 2603)	1.04 (0.75, 1.60)	0.08 (0.00, 0.77)
		OMBP +/- enema vs. no prep	11 (95 / 2104 vs. 99 / 2073)	1.02 (0.69, 1.71)	0.09 (0.00, 1.03)
		OMBP +/- enema vs. enema	4 (24 / 526 vs. 21 / 530)	1.24 (0.38, 4.72)	0.61 (0.00, 3.59)
	Wound infection	OMBP vs. no OMBP	15 (249 / 2540 vs. 230 / 2526)	1.13 (0.88, 1.53)	0.03 (0.00, 0.37)
		OMBP +/- enema vs. no prep	11 (201 / 2014 vs. 181 / 1996)	1.19 (0.88, 1.77)	0.03 (0.00, 0.48)
		OMBP +/- enema vs. enema	4 (48 / 526 vs. 49 / 530)	1.04 (0.37, 3.34)	0.52 (0.00, 3.46)
Exclude Tahirkheli, 2013	All cause mortality	OMBP vs. no OMBP	14 (45 / 2550 vs. 44 / 2544)	1.17 (0.67, 2.67)	0.12 (0.00, 1.99)
		OMBP +/- enema vs. no prep	10 (38 / 2024 vs. 40 / 2014)	1.09 (0.57, 2.99)	0.17 (0.00, 2.61)
		OMBP +/- enema vs. enema	4 (7 / 526 vs. 4 / 530)	1.99 (0.27, 18.45)	0.82 (0.00, 3.76)
	Anastomotic leakage	OMBP vs. no OMBP	15 (118 / 2654 vs. 118 / 2632)	1.07 (0.76, 1.67)	0.10 (0.00, 0.87)
		OMBP +/- enema vs. no prep	11 (94 / 2128 vs. 97 / 2102)	1.04 (0.69, 1.80)	0.11 (0.00, 1.15)
		OMBP +/- enema vs. enema	4 (24 / 526 vs. 21 / 530)	1.24 (0.38, 4.72)	0.61 (0.00, 3.59)
	Wound infection	OMBP vs. no OMBP	16 (266 / 2612 vs. 239 / 2603)	1.19 (0.93, 1.63)	0.04 (0.00, 0.41)
		OMBP +/- enema vs. no prep	12 (218 / 2086 vs. 190 / 2073)	1.27 (0.95, 1.88)	0.05 (0.00, 0.50)
		OMBP +/- enema vs. enema	4 (48 / 526 vs. 49 / 530)	1.04 (0.37, 3.34)	0.52 (0.00, 3.46)

CI = confidence interval; OMBP = oral mechanical bowel preparation; OR = odds ratio; prep = preparation; SSI = surgical site infection.

Appendix D. Sensitivity Analysis for Pairwise Contrasts Using Bayesian Methods (Alternative Prior Specification)

Please consult Turner et al., International Journal of Epidemiology 2012, for details regarding prior selection.

Appendix Table D1. Sensitivity analysis for pairwise meta-analysis (using alternative priors)

Outcome	Prior distribution for between-study variance	Comparison	N studies (N events / N patients, per group)	OR (95% CrI)	Between-study variance (95% CrI)
All cause mortality	Informative, log-normal, mortality, pharmacologic intervention vs. control	OMBP vs. no OMBP	14 (45 / 2550 vs. 44 / 2544)	1.08 (0.68, 1.75)	0.02 (0.00, 0.21)
		OMBP +/- enema vs. enema	4 (7 / 526 vs. 4 / 530)	1.87 (0.53, 7.78)	0.02 (0.00, 0.30)
		OMBP +/- enema vs. no prep	10 (38 / 2024 vs. 40 / 2014)	0.96 (0.60, 1.66)	0.01 (0.00, 0.19)
	Uninformative, U(0,5)	OMBP vs. no OMBP	14 (45 / 2550 vs. 44 / 2544)	1.17 (0.66, 2.84)	0.15 (0.00, 2.32)
		OMBP +/- enema vs. enema	4 (7 / 526 vs. 4 / 530)	2.01 (0.04, 134.30)	3.27 (0.01, 22.73)
		OMBP +/- enema vs. no prep	10 (38 / 2024 vs. 40 / 2014)	1.12 (0.57, 3.35)	0.18 (0.00, 4.16)
Anastomotic leakage	Informative, log-normal, semi-objective outcomes, pharmacologic intervention vs. control	OMBP vs. no OMBP	16 (126 / 2702 vs. 124 / 2680)	1.05 (0.79, 1.48)	0.03 (0.00, 0.33)
		OMBP +/- enema vs. enema	4 (24 / 526 vs. 21 / 530)	1.19 (0.57, 2.55)	0.05 (0.00, 1.21)
		OMBP +/- enema vs. no prep	12 (102 / 2176 vs. 103 / 2150)	1.03 (0.75, 1.52)	0.03 (0.00, 0.39)
	Uninformative, U(0,5)	OMBP vs. no OMBP	16 (126 / 2702 vs. 124 / 2680)	1.09 (0.79, 1.63)	0.09 (0.00, 0.72)
		OMBP +/- enema vs. enema	4 (24 / 526 vs. 21 / 530)	1.25 (0.22, 9.49)	1.02 (0.00, 16.70)
		OMBP +/- enema vs. no prep	12 (102 / 2176 vs. 103 / 2150)	1.07 (0.73, 1.76)	0.10 (0.00, 0.94)
Wound infection	Informative, log-normal, semi-objective outcomes, pharmacologic intervention vs. control	OMBP vs. no OMBP	16 (266 / 2612 vs. 239 / 2603)	1.18 (0.93, 1.53)	0.02 (0.00, 0.20)
		OMBP +/- enema vs. enema	4 (48 / 526 vs. 49 / 530)	1.00 (0.57, 1.91)	0.06 (0.00, 1.11)
		OMBP +/- enema vs. no prep	12 (218 / 2086 vs. 190 / 2073)	1.24 (0.96, 1.72)	0.02 (0.00, 0.23)
	Uninformative, U(0,5)	OMBP vs. no OMBP	16 (266 / 2612 vs. 239 / 2603)	1.19 (0.93, 1.63)	0.04 (0.00, 0.43)
		OMBP +/- enema vs. enema	4 (48 / 526 vs. 49 / 530)	1.04 (0.23, 5.48)	0.70 (0.00, 13.59)
		OMBP +/- enema vs. no prep	12 (218 / 2086 vs. 190 / 2073)	1.27 (0.95, 1.90)	0.05 (0.00, 0.49)
Peritonitis	Informative, log-normal, semi-objective outcomes, pharmacologic intervention vs.	OMBP vs. no OMBP	14 (51 / 2381 vs. 70 / 2362)	0.77 (0.51, 1.30)	0.05 (0.00, 0.59)
		OMBP +/- enema vs. enema	4 (6 / 526 vs. 6 / 530)	0.98 (0.27, 3.43)	0.04 (0.00, 0.88)

	control	OMBP +/- enema vs. no prep	10 (45 / 1855 vs. 64 / 1832)	0.76 (0.48, 1.40)	0.07 (0.00, 0.89)
	Uninformative, U(0,5)	OMBP vs. no OMBP	14 (51 / 2381 vs. 70 / 2362)	0.84 (0.50, 1.66)	0.24 (0.00, 1.84)
		OMBP +/- enema vs. enema	4 (6 / 526 vs. 6 / 530)	1.01 (0.13, 7.78)	0.68 (0.00, 16.23)
		OMBP +/- enema vs. no prep	10 (45 / 1855 vs. 64 / 1832)	0.85 (0.44, 2.20)	0.42 (0.00, 3.94)
Reoperation	Informative, log-normal, semi-objective outcomes, pharmacologic intervention vs. control	OMBP vs. no OMBP	8 (124 / 1967 vs. 119 / 1945)	1.09 (0.75, 1.73)	0.04 (0.00, 0.86)
		OMBP +/- enema vs. enema	2 (7 / 225 vs. 8 / 222)	0.64 (0.01, 5.57)	0.91 (0.00, 17.18)
		OMBP +/- enema vs. no prep	6 (117 / 1742 vs. 111 / 1723)	1.10 (0.78, 1.72)	0.03 (0.00, 0.41)
	Uninformative, U(0,5)	OMBP vs. no OMBP	8 (124 / 1967 vs. 119 / 1945)	1.14 (0.50, 2.94)	0.43 (0.00, 6.44)
		OMBP +/- enema vs. enema	2 (7 / 225 vs. 8 / 222)	0.21 (0.00, 43.38)	13.05 (1.52, 24.37)
		OMBP +/- enema vs. no prep	6 (117 / 1742 vs. 111 / 1723)	1.15 (0.72, 2.63)	0.10 (0.00, 2.41)
SSI	Informative, log-normal, semi-objective outcomes, pharmacologic intervention vs. control	OMBP vs. no OMBP	7 (206 / 1279 vs. 197 / 1230)	1.16 (0.68, 2.10)	0.30 (0.03, 1.38)
		OMBP +/- enema vs. enema	2 (33 / 192 vs. 26 / 190)	1.39 (0.54, 4.30)	0.13 (0.00, 2.27)
		OMBP +/- enema vs. no prep	5 (173 / 1087 vs. 171 / 1040)	1.06 (0.57, 2.14)	0.27 (0.02, 1.64)
	Uninformative, U(0,5)	OMBP vs. no OMBP	7 (206 / 1279 vs. 197 / 1230)	1.19 (0.55, 2.77)	0.64 (0.11, 4.10)
		OMBP +/- enema vs. enema	2 (33 / 192 vs. 26 / 190)	1.51 (0.03, 85.24)	3.73 (0.06, 22.89)
		OMBP +/- enema vs. no prep	5 (173 / 1087 vs. 171 / 1040)	1.10 (0.34, 3.82)	0.85 (0.11, 9.19)

CI = confidence interval; OMBP = oral mechanical bowel preparation; OR = odds ratio; prep = preparation; SSI = surgical site infection.

Appendix E. Sensitivity Analysis for Pairwise Contrasts Using Frequentist Methods (No Prior Specification)

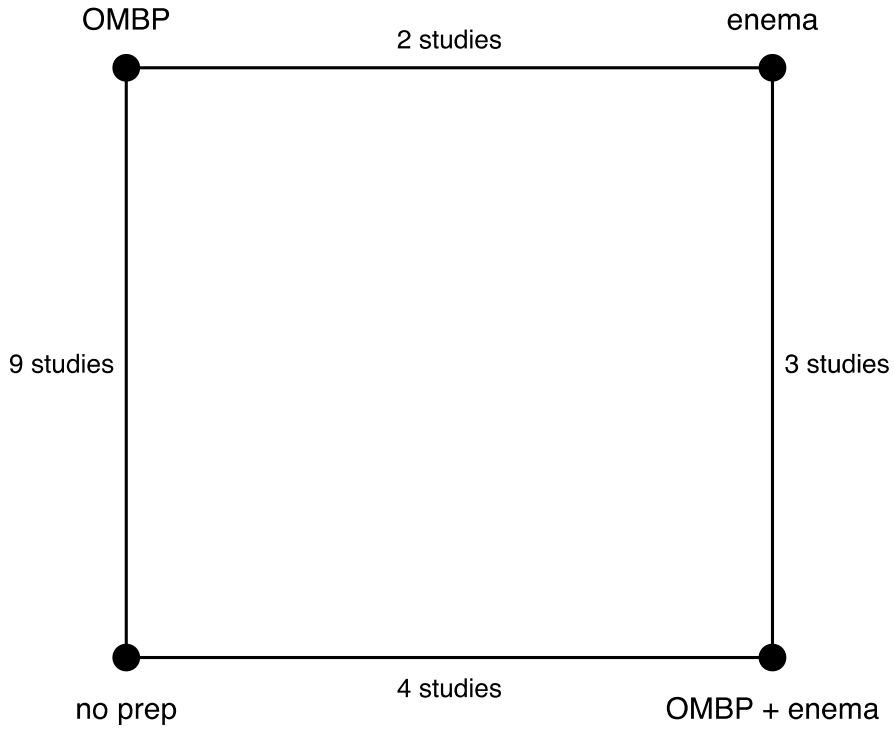
Appendix Table E1. Meta-analysis results using frequentist methods

Outcome	Comparison	N studies (N events / N patients, per group)	OR (95% CI); P value	Heterogeneity (P_Q; I^2)
All cause mortality	OMBP +/- enema vs. no OMBP	14 (45 / 2550 vs. 44 / 2544)	1.00 (0.65, 1.53); P = 0.99	0.86; 0%
	OMBP +/- enema vs. no prep	10 (38 / 2024 vs. 40 / 2014)	0.94 (0.60, 1.48); P = 0.78	0.88; 0%
	OMBP +/- enema vs. enema	4 (7 / 526 vs. 4 / 530)	1.67 (0.45, 6.13); P = 0.44	0.32; 0%
Anastomotic leakage	OMBP +/- enema vs. no OMBP	16 (126 / 2702 vs. 124 / 2680)	1.00 (0.76, 1.31); P = 1.00	0.43; 2%
	OMBP +/- enema vs. no prep	12 (102 / 2176 vs. 103 / 2150)	0.97 (0.73, 1.30); P = 0.84	0.48; 0%
	OMBP +/- enema vs. enema	4 (24 / 526 vs. 21 / 530)	1.16 (0.51, 2.64); P = 0.71	0.21; 34%
Wound infection	OMBP +/- enema vs. no OMBP	16 (266 / 2612 vs. 239 / 2603)	1.13 (0.94, 1.36); P = 0.21	0.46; 0%
	OMBP +/- enema vs. no prep	12 (218 / 2086 vs. 190 / 2073)	1.17 (0.95, 1.45); P = 0.14	0.71; 0%
	OMBP +/- enema vs. enema	4 (48 / 526 vs. 49 / 530)	1.02 (0.53, 1.93); P = 0.96	0.11; 50%
Peritonitis	OMBP +/- enema vs. no OMBP	14 (51 / 2381 vs. 70 / 2362)	0.71 (0.48, 1.04); P = 0.08	0.54; 0%
	OMBP +/- enema vs. no prep	10 (45 / 1855 vs. 64 / 1832)	0.75 (0.46, 1.24); P = 0.26	0.29; 17%
	OMBP +/- enema vs. enema	4 (6 / 526 vs. 6 / 530)	1.00 (0.31, 3.24); P = 0.99	0.87; 0%
Reoperation	OMBP +/- enema vs. no OMBP	8 (124 / 1967 vs. 119 / 1945)	1.15 (0.77, 1.70); P = 0.50	0.19; 29%
	OMBP +/- enema vs. no prep	6 (117 / 1742 vs. 111 / 1723)	1.04 (0.79, 1.37); P = 0.76	0.49; 0%
	OMBP +/- enema vs. enema	2 (7 / 225 vs. 8 / 222)	0.61 (0.01, 32.65); P = 0.81	0.02; 83%
SSI	OMBP +/- enema vs. no OMBP	7 (206 / 1279 vs. 197 / 1230)	1.17 (0.70, 1.95); P = 0.55	0.00; 74%
	OMBP +/- enema vs. no prep	5 (173 / 1087 vs. 171 / 1040)	1.08 (0.59, 2.00); P = 0.79	0.00; 77%
	OMBP +/- enema vs. enema	2 (33 / 192 vs. 26 / 190)	1.51 (0.38, 6.06); P = 0.56	0.02; 81%

CI = confidence interval; OMBP = oral mechanical bowel preparation; OR = odds ratio; SSI = surgical site infection.

Appendix F. Structural Sensitivity Analysis for Network Meta-Analysis (4-Node Network Structure)

Appendix Figure F1. 4-node network structure used in sensitivity analysis



OMBP = oral mechanical bowel preparation; prep = preparation.

Appendix Table F1. Summary estimates from the 4-node network meta-analysis

Outcome	Comparison	OR (95% CrI)
All cause mortality	OMBP vs. no preparation	1.06 (0.43, 5.78)
	OMBP + enema vs. no preparation	1.31 (0.26, 9.32)
	OMBP vs. enema	4.68 (0.27, 205.40)
	OMBP + enema vs. enema	5.61 (0.14, 388.46)
Anastomotic leakage	OMBP vs. no preparation	1.09 (0.70, 1.97)
	OMBP + enema vs. no preparation	1.00 (0.46, 2.41)
	OMBP vs. enema	0.75 (0.21, 2.31)
	OMBP + enema vs. enema	0.68 (0.21, 2.00)
Wound infection	OMBP vs. no preparation	1.23 (0.87, 1.97)
	OMBP + enema vs. no preparation	1.42 (0.81, 2.61)
	OMBP vs. enema	0.66 (0.30, 1.37)
	OMBP + enema vs. enema	0.76 (0.32, 1.65)
Peritonitis/ Intra-abdominal abscess	OMBP vs. no preparation	0.73 (0.31, 2.22)
	OMBP + enema vs. no preparation	1.18 (0.35, 5.07)
	OMBP vs. enema	1.31 (0.10, 20.41)
	OMBP + enema vs. enema	2.10 (0.17, 31.49)

*Based only on indirect comparisons.

CrI = credible interval; OMBP = oral mechanical bowel preparation; OR = odds ratio.

Appendix G. Ongoing Studies

Appendix Table G1. Ongoing studies

Clinical Trial Identifier	Study name	Status as of May 15, 2013	Availability of results	Population	Comparison
NCT01797770	Trial on Mechanical Bowel Preparation in Laparoscopic Colorectal Surgery	Recruiting	NA	colon and rectal cancer	OMBP vs. no preparation
NCT00687570	Bowel Preparation Before Rectal Cancer Surgery	Recruiting	NA	rectal cancer	OMBP vs. nutritional
NCT00940030	Comparison of Mechanical Bowel Preparation Versus Enema for Candidates to Colorectal Resection for Adenocarcinoma	Recruiting	NA	colorectal cancer	OMBP vs. enema
NCT00643084	Bowel Prep vs. Non-Bowel Prep for Laparoscopic Colorectal Surgery	Not yet recruiting	NA	colorectal surgery	OMBP vs. no preparation
NCT00618930	Moviprep Versus Fleet Phospho-Soda (Golden Standard): A Study That Compared Two Laxatives on Patients Undergoing Colo-Rectal Cleansing Prior to an Abdominal Operation	Completed	NA	colorectal surgery	Comparison of two OMBP strategies

NA = not available; OMBP = oral mechanical bowel preparation.